2019 surveillance of menopause (NICE guideline NG23)

Surveillance proposal

We propose to not update the guideline on menopause.

Reasons for the proposal not to update the guideline

Managing urogenital atrophy

We identified new evidence on ospemifene, which is licensed in the UK for treating urogenital atrophy in women who are not candidates for vaginal oestrogen. At the time of guideline development, ospemifene had received a UK marketing authorisation but information on its cost was not available for consideration in the related evidence review. The situation has changed because the treatment is now available (costing £39.50 for 28 tablets) and new evidence indicates that it may improve sexual function, vaginal dryness, and dyspareunia. However, the new evidence did not report on adverse events associated with ospemifene. It was not possible to tell from the abstracts whether the effects were clinically meaningful, or durable.

We also identified new evidence for prasterone use for up to 3 months. Prasterone has recently been licensed in the UK (costing £15.94 for 28 pessaries) for treating vulvar and vaginal atrophy in postmenopausal women having moderate to severe symptoms. Further evidence on the effects with prasterone treatment longer than 3 months and longer-term safety data is needed before considering an update of the guideline to evaluate the role of prasterone for treating vaginal symptoms of the menopause.

The cost of prasterone is comparable with available intravaginal oestrogen pessaries, and although ospemifene is more expensive, its use is restricted to a smaller group of women for whom intravaginal oestrogen is not suitable. Therefore, we do not expect these treatments to have a substantial impact on NHS resources. Additionally, we are not aware of any new safety issues relating to other currently recommended treatments for vaginal symptoms of

menopause. For these reasons, we decided that an update was not necessary at this time.

New evidence for other treatments for short-term menopausal symptoms was identified: including drug treatments, psychological treatments, and alternative medicine and complementary therapies. However, the evidence for these treatments did not indicate a need to update the guideline because each intervention was usually assessed in a single small trial, which was deemed insufficient to change existing recommendations.

Long-term benefits and risks of hormone replacement therapy

We identified new evidence on the long-term risks and benefits of hormone replacement therapy. This included areas covered by the guideline such as cardiovascular outcomes, cancer outcomes, osteoporosis and dementia. The findings were generally consistent with the guideline. New evidence did not suggest that an update of the guideline is needed to consider additional risks or benefits of hormone replacement therapy.

For further details and a summary of all evidence identified in surveillance, see summary of evidence from surveillance.

Overview of 2019 surveillance methods

NICE's surveillance team checked whether recommendations in menopause (NICE guideline NG23) remain up to date.

The surveillance process consisted of:

- Feedback from topic experts via a questionnaire.
- A search for new or updated Cochrane reviews.
- Examining related NICE guidance and quality standards and NIHR signals.
- A search for ongoing research.
- Examining the NICE event tracker for relevant ongoing and published events.
- Literature searches to identify relevant evidence.

- Assessing the new evidence against current recommendations to determine whether or not to update sections of the guideline, or the whole guideline.
- Consulting on the proposal with stakeholders (this document).

For further details about the process and the possible update decisions that are available, see ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual.

Evidence considered in surveillance

Search and selection strategy

We searched for new evidence related to the whole guideline.

We found 122 studies in a search for randomised controlled trials (RCTs), Cochrane reviews and observational studies published between 13 January 2015 and 07 May 2019.

We also included 5 relevant studies from a total of 12 identified by topic experts, all of which were also identified by the searches.

From all sources, we considered 122 studies to be relevant to the guideline.

Selecting relevant studies

We included RCTs that had at least 100 participants because of a large volume of small studies.

Ongoing research

We checked for relevant ongoing research; of the ongoing studies identified, 2 studies were assessed as having the potential to change recommendations. Therefore, we plan to check the publication status regularly and evaluate the impact of the results on current recommendations as quickly as possible. These studies are:

- Effect of Menopause Relief EP-40 in Women With Menopausal Symptoms (NCT03461380)

  - This randomised controlled trial is assessing complementary therapies, including two doses of standardised black cohosh. The guideline noted 'there is some evidence that isoflavones or black cohosh may relieve vasomotor symptoms…' but that 'multiple preparations are available and their safety is uncertain, different preparations may vary and interactions with other medicines have been reported'. This ongoing study may provide further evidence in this area.
- Can nurse delivered cognitive behavioural therapy reduce the impact of hot flushes and night sweats in women who have had breast cancer? (ISRCTN12824632)
  - This randomised controlled trial is assessing the effects of cognitive behavioural therapy on vasomotor symptoms of menopause.

Intelligence gathered during surveillance

Views of topic experts

We considered the views of topic experts who were recruited to the NICE Centre for Guidelines Expert Advisers Panel to represent their specialty. For this surveillance review, topic experts completed a questionnaire about developments in evidence, policy and services related to the guideline.

We sent questionnaires to 13 topic experts and received 7 responses. The topic experts who provided feedback were: GPs with a special interest in gynaecology and women's health, nurse consultants in gynaecology, consultant gynaecologist, academic clinical psychologist, and a consultant medical oncologist with a special interest in breast cancer.

Overall, 3 topic experts thought that the guideline should be updated and 4 thought that an update was not necessary. The issues that topic experts thought could be addressed in an update were:

- Expanding on recommendations for women with breast cancer (and other hormone-dependent cancers), for example how treatments for vaginal atrophy might differ for women on tamoxifen and those on aromatase inhibitors. There is some overlap across NICE guidelines, particularly in the

guidelines on early and locally advanced breast cancer and familial breast cancer. The guideline on menopause already has cross-references to the breast cancer guidelines. These guidelines have more detailed recommendations for women with or at risk of breast cancer who have treatment-related menopausal symptoms. We did not find sufficient new evidence to support an update of the menopause guideline in this area.

- Alternative and complementary therapies were highlighted, but new evidence did not confirm a clear need to update in this area. We found one ongoing study of black cohosh that may provide further evidence in this area; we will regularly check for publication of results from this study.
- Psychological therapies for vasomotor symptoms and depression, but new evidence did not confirm a clear need to update in these areas. Postmenopausal women meeting criteria for generalised anxiety or depression should receive treatment according to the relevant NICE guidelines.We found an ongoing study of cognitive behavioural therapy for managing hot flushes and night sweats in women who have had breast cancer; we will regularly check for publication of results from this study.
- Topic experts had conflicting views on the rate of uptake of the guideline in their local services.

Views of stakeholders

Stakeholders are consulted on all surveillance reviews except if the whole guideline will be updated and replaced. Because this surveillance proposal is to not update part of the guideline, we are consulting with stakeholders.

See ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual for more details on our consultation processes.

Equalities

No equalities issues were identified during the surveillance process.

Editorial amendments

During surveillance of the guideline we identified the following points in the guideline that should be amended.

On the overview page the following text should be deleted:

'In **November 2015**, the Medicines and Healthcare products Regulatory Agency (MHRA) was consulting with marketing authorisation holders on amending the existing warning about the risk of ovarian cancer in the summary of product characteristics (SPC) information for hormone replacement therapy (HRT) products.'

SPCs for HRT products have been updated in line with a 2015 European Medicines Agency recommendation so this statement is now redundant.

In recommendation 1.4.25, the cross-reference to section 1.13 of the NICE guideline on early and locally advanced breast cancer should be amended because that guideline has been updated and the cross-reference is now out of date. The hyperlink should also be updated from the previous guideline so that users go directly to the updated guideline.

Overall decision

After considering all evidence and other intelligence and the impact on current recommendations, we propose that no update is necessary.