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NICE guideline – Menopause: diagnosis and management

Starting and stopping HRT (Section 10)

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Menopause, starting HRT, stopping HRT

Introduction

This summary deals with the recommendations from the guidelines in respect to starting, continuing or stopping hormone replacement therapy (HRT) and the advice which should be given to menopausal women.

The guideline devotes section 10 to starting and stopping HRT but only provides guidance in respect to stopping HRT. There are, however, recommendations throughout the guideline in respect to starting HRT which form the basis of the following statements, which, therefore, overlap to some extent with some summaries from other sections of the guideline.

Evaluate and advise prior to starting treatment

- An individualised approach should be adopted at all stages of care (1.3.1), with information given in different ways (1.3.10). Menopausal women should be offered an explanation of the stages of the menopause (1.3.7). They should be advised that as well as expecting a change in their menstrual cycle, they might experience symptoms such as hot flushes and night sweats (vaso-motor symptoms), muscle aches and pains, mood changes, vaginal dryness and sexual difficulties (1.3.8).
- They should be advised of the lifestyle changes which would help their general health and well-being and should be advised of the different treatments for menopausal symptoms (hormonal, non-hormonal and non-pharmaceutical) (1.3.9) and the benefits and risks of treatments (1.3.7).
- Women about to have medical or surgical treatment which will precipitate menopause should be advised what to expect before their treatment and should be referred to a health care professional with expertise in menopause (1.3.12. 7.8.12).

Starting HRT

- HRT should be offered for flushes and sweats after discussing both short term and longer term benefits and risks, offering estrogen alone to a woman without a uterus and estrogen and progestogen to a woman with a uterus (1.3.14. 8.2.8.14).
- Consider HRT for women with anxiety and mood changes that arise as a result of the menopause (1.3.17, 8.2.8.17).
- Consider transdermal HRT for women who have an increased risk of venous-thrombo embolic (VTE) disease including those with a BMI over 30. (1.3.40) but consider referring those at high risk of VTE before starting HRT for haematological advice (1.3.41).
- Testosterone supplementation should be considered for women with reduced libido (sexual desire) if estrogen replacement is not effective alone. (1.3.20, 8.2.8.20).
- Women with Type 2 diabetes should be offered HRT after taking co-morbidities into account. Seek specialist advice if required (1.3.48).

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- Consider referral to a professional with expertise in menopause (1.3.35. 9.8.35) when it is not clear which are the best treatment options.
- Treatment for women with breast cancer or at high risk of breast cancer is explored in section 1.7 of the 2013 NICE guideline on familial breast cancer[1] (8.2.24).

Explanation of risk for women and health care professionals prior to starting, using Tables 1–4[1]

Cardiovascular disease and stroke

- HRT does not increase risk or risk from dying of cardiovascular disease when started under 60 (1.3.42).
- Cardiovascular risk factors should be managed optimally but are not a reason for withholding HRT (1.3.43).
- Baseline risk of cardiovascular disease and stroke is dependent on personal underlying risk factors (1.3.44).
- Estrogen alone may reduce (and does not increase) the risk of coronary heart disease (1.3.44).
- 'HRT with estrogen and progestogen is associated with little or no increase in the risk of coronary heart disease'[2] (1.3.44).
- Oral but not transdermal estrogen may cause a very small increased risk of stroke 'but the baseline population risk of stroke in women aged under 60 years is very low'[2] (1.3.45).

Diabetes

- HRT either orally or transdermally does not affect blood glucose control or increase the risk of developing Type 2 diabetes (1.3.47).

Breast Cancer

- HRT does not increase risk of death from breast cancer (1.3.49).
- Baseline risk of breast cancer is dependent on underlying personal risk factors (1.3.50).
- HRT with estrogen alone does not increase the risk of breast cancer (1.3.50).
- HRT with estrogen and progestogen can be associated with an increase in the risk of breast cancer'[2] but that 'any increase in the risk of breast cancer is related to the length of treatment and reduces after stopping HRT'[2] (11.5.8.49).

Venous thromboembolic disease

- Oral HRT will increase the risk of VTE, but transdermal HRT at standard dose does not alter baseline risk (1.3.39).

Moderate quality evidence showed that women would like more information about HRT from their health professionals. Internet evidence is confusing, and women would like their health professionals to be more involved in the decision making.

Starting vaginal estrogen

- Women with atrophic symptoms, including those on systemic HRT, should be offered low dose vaginal estrogen and should continue on treatment as long as needed to alleviate symptoms (1.3.26) (8.3.8.26).
- Treatment for urogenital atrophy needs to be commenced before irreversible change has occurred and continued in order to maintain benefit. Vaginal local estrogens are very safe (8.3.7.2), adverse effects from vaginal estrogen are unusual (8.3.8.29), but unscheduled bleeding should be reported to the GP (8.3.8.29).
- Local estrogen therapy can be used long term, ultrasound measurement of endometrial thickness is not required (8.3.7.2, 8.3.8.31).
- Estradiol tablets are available only at '10 micrograms and a dose of 20 micrograms may be required'[2] for which there is good supportive evidence (8.3.7.2).
- Vaginal estrogens may also be considered for women in whom systemic HRT is contraindicated as there is minimal systemic absorption (1.3.27, 8.3.7.2), but advice should be sought from a health care professional with expertise in menopause care for those women whose symptoms of urogenital atrophy are not relieved by low dose vaginal estrogen (and consider increasing the dose) (1.3.28) (8.3.8.28) or for whom systemic HRT is contraindicated (1.3.27) (8.3.8.27).

Premature ovarian insufficiency

Women with early menopause should be offered sex steroid replacement. Both HRT and the combined oral contraceptive is suitable 'unless contraindicated (e.g. in women with hormone sensitive cancer)'[2] (1.3.61). They should be told about the importance of starting hormonal treatment and continuing at least until the age of expected menopause. Both HRT and COC are bone protective, HRT is not a contraceptive, and HRT may improve blood pressure (1.3.62).

Continuing HRT

To 'maximise health benefits, improve compliance with medication and address any adverse effects'[2] women should work in partnership with their health care professionals (9.1).

- Treatment for short-term menopausal symptoms should be reviewed initially at three months and thereafter annually unless the treatment is not helpful or if there are side effects or adverse events (1.3.33, 9.8.33).
- Refer to a menopause specialist if there are persistent problems (1.3.34, 9.8.34).
- In discussing continuation, the benefits and risks should be reviewed so that women are aware of what to expect when treatment is stopped (10.1).
- Women's symptoms often change and health care professionals should be aware of the need to adjust to these changes (8.2.8.13).
- Women have previously been 'advised to stop HRT after two to five years of use or at the age of 60',[2] but the guidelines states that there is no certain evidence for this advice (10.1).

Evidence. There is an absence of clinical evidence for clinical benefit and harm in respect to review and referral, and recommendations for referral and review were made based on the clinical experience of the guidance group (9.7.2).

Continuing vaginal estrogen

- Women on low-dose vaginal estrogen should stay on treatment for as long as is needed (1.3.26) (8.3.26).
- Local estrogen can be used long term as the 'systemic absorption of estrogen from recommended dosages is very small'[2] (8.3.7.2).
- Monitoring of endometrial thickness during treatment is not recommended (1.3.31) (8.3.8.31).
- It is important to report unscheduled vaginal bleeding to the health care professional (1.3.29).

Evidence. Quality was moderate to very low, but there was one case of endometrial hyperplasia associated with local estrogens used over a long period (8.3.7.2). The guidelines consider the risk is too low to suggest regular ultrasound evaluation of endometrial lining in women using local estrogens (1.3.23), but there is little long-term follow-up data (8.3.7.4).

Stopping systemic HRT

- In the first three months of treatment, women often experience unscheduled vaginal bleeding which is not a reason to stop but which should be reported at review appointments, or promptly if it occurs after the first three months (1.3.36, 10.7.2, 10.8.36).
- Women who are stopping HRT should be offered the choice of either immediately or gradually reducing their HRT (1.3.37, 10.8.37). A gradually reduction of HRT may limit recurrent symptoms in the short term (1.3.38. 10.8.38).
- Breast cancer risk is linked to longer treatment use and reduces after stopping HRT (1.3.50).
- Fragility fracture risk is decreased whilst taking HRT but decreases once treatment stops (1.3.53).

Evidence for advice given regarding stopping HRT

There were a variety of different methods of tapering and follow-up time of outcomes varied. Outcomes assessed were vasomotor, quality of life, return to HRT or use of alternatives. The evidence statements were based on low to very low quality evidence. It was considered that a woman's personal preference was most important (10.7.2).

The key conclusion is that evidence is not conclusive and the clinical experience from the CGG was used to inform the decision making (10.7.6).

There are no recommendations for future research in this area.

Stopping vaginal estrogen

- Women should be advised that symptoms of urogenital atrophy often come back when treatment is stopped (1.3.29, 8.3.29).

Key points

Starting HRT

1. Evaluate and advise women in different ways about what symptoms to expect, how to help themselves and of the risks and benefits of all treatments.
2. Choose estrogen alone for women without a uterus, and progestogen and estrogen for women with a uterus, use transdermal for patients at higher risk of venous thromboembolic disease (after considering haematology referral) or a BMI above 30.
3. Consider HRT (oral or transdermal) for patients with diabetes.
4. Evaluate risk using tables as provided.

5. Low-dose vaginal estrogen is very safe and should be used for women with urogenital symptoms as well as those on systemic HRT and may be considered for women with contraindications to HRT. Consider increasing the dose if necessary and continue as long as is needed to relieve symptoms. Referral to a menopause specialist may be required. Monitoring of the endometrium is not required.
6. Women with early menopause should have an explanation of the importance of HRT and offered the choice of either HRT or COC, unless contraindicated.

Continuing HRT

1. Review at three months and thereafter annually, unless there are adverse or side effects, or treatment failure.
2. Ensure a woman is advised of what to expect if she stops treatment and consider referral to a menopause specialist if there are persistent problems.

Stopping HRT

1. Unscheduled vaginal bleeding in the first three months is a common side effect of systemic HRT, and women should be advised not to stop HRT if this occurs but to report it at review appointments, and more urgently if more than three months after starting.
2. Unscheduled bleeding on vaginal estrogen should be reported to the GP.
3. There is uncertain evidence for the previous advice to stop after two to five years or at the age of 60.
4. When women wish to stop HRT, they may choose to stop abruptly or gradually reduce.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Provenance

Commissioned; internally reviewed.

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2. National Institute for Health and Care Excellence. Menopause: clinical guideline – methods, evidence and recommendations (NG23), Version 1.5, https://www.nice.org.uk/guidance/ng23/evidence/full-guideline-559549261 (2015, 22 April 2016).