

# Menopause: diagnosis and management

NICE guideline

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## Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

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This guideline is the basis of QS143.

## Overview

This guideline covers the diagnosis and management of menopause, including in women who have premature ovarian insufficiency. The guideline aims to improve the consistency of support and information provided to women in menopause.

### *Who is it for?*

- Healthcare professionals who care for women in menopause.
- Women in menopause, and their families and carers.

## Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in [your care](#).

[Making decisions using NICE guidelines](#) explains how we use words to show the strength of our recommendations, and has information about safeguarding, consent and prescribing medicines (including 'off-label' use).

### 1.1 *Individualised care*

1.1.1 Adopt an individualised approach at all stages of diagnosis, investigation and management of menopause. Follow recommendations in the NICE guideline on [patient experience in adult NHS services](#).

### 1.2 *Diagnosis of perimenopause and menopause*

1.2.1 Diagnose the following without laboratory tests in otherwise healthy women aged over 45 years with menopausal symptoms:

- perimenopause based on vasomotor symptoms and irregular periods
- menopause in women who have not had a period for at least 12 months and are not using hormonal contraception
- menopause based on symptoms in women without a uterus.

1.2.2 Take into account that it can be difficult to diagnose menopause in women who are taking hormonal treatments, for example for the treatment of heavy periods.

1.2.3 Do not use the following laboratory and imaging tests to diagnose perimenopause or menopause in women aged over 45 years:

- anti-Müllerian hormone
- inhibin A
- inhibin B
- oestradiol

- antral follicle count
- ovarian volume.

1.2.4 Do not use a serum follicle-stimulating hormone (FSH) test to diagnose menopause in women using combined oestrogen and progestogen contraception or high-dose progestogen.

1.2.5 Consider using a FSH test to diagnose menopause only:

- in women aged 40 to 45 years with menopausal symptoms, including a change in their menstrual cycle
- in women aged under 40 years in whom menopause is suspected (see also [section 1.6](#)).

### 1.3 *Information and advice*

1.3.1 Give information to menopausal women and their family members or carers (as appropriate) that includes:

- an explanation of the stages of menopause
- common symptoms (see recommendation 1.3.2) and diagnosis
- lifestyle changes and interventions that could help general health and wellbeing
- benefits and risks of treatments for menopausal symptoms
- long-term health implications of menopause.

1.3.2 Explain to women that as well as a change in their menstrual cycle they may experience a variety of symptoms associated with menopause, including:

- vasomotor symptoms (for example, hot flushes and sweats)
- musculoskeletal symptoms (for example, joint and muscle pain)
- effects on mood (for example, low mood)
- urogenital symptoms (for example, vaginal dryness)
- sexual difficulties (for example, low sexual desire).

1.3.3 Give information to menopausal women and their family members or carers (as appropriate) about the following types of treatment for menopausal symptoms:

- hormonal, for example hormone replacement therapy (HRT)
- non-hormonal, for example clonidine
- non-pharmaceutical, for example cognitive behavioural therapy (CBT).

1.3.4 Give information on menopause in different ways to help encourage women to discuss their symptoms and needs.

1.3.5 Give information about contraception to women who are in the perimenopausal and postmenopausal phase. See guidance from the Faculty of Sexual & Reproductive Healthcare on [contraception for women aged over 40 years](#).

1.3.6 Offer women who are likely to go through menopause as a result of medical or surgical treatment (including women with cancer, at high risk of hormone-sensitive cancer or having gynaecological surgery) support and:

- information about menopause and fertility before they have their treatment
- referral to a healthcare professional with expertise in menopause.

## 1.4 *Managing short-term menopausal symptoms*

The recommendations in this section are not intended for women with premature ovarian insufficiency (see recommendations [1.6.6 to 1.6.8](#) for management of premature ovarian insufficiency).

1.4.1 Adapt a woman's treatment as needed, based on her changing symptoms.

### **Vasomotor symptoms**

1.4.2 Offer women HRT for vasomotor symptoms after discussing with them the short-term (up to 5 years) and longer-term benefits and risks. Offer a choice of preparations as follows:

- oestrogen and progestogen to women with a uterus

- oestrogen alone to women without a uterus.

1.4.3 Do not routinely offer selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs) or clonidine as first-line treatment for vasomotor symptoms alone.

1.4.4 Explain to women that there is some evidence that isoflavones or black cohosh may relieve vasomotor symptoms. However, explain that:

- multiple preparations are available and their safety is uncertain
- different preparations may vary
- interactions with other medicines have been reported.

### Psychological symptoms

1.4.5 Consider HRT to alleviate low mood that arises as a result of the menopause.

1.4.6 Consider CBT to alleviate low mood or anxiety that arise as a result of the menopause.

1.4.7 Ensure that menopausal women and healthcare professionals involved in their care understand that there is no clear evidence for SSRIs or SNRIs to ease low mood in menopausal women who have not been diagnosed with depression (see the NICE guideline on [depression in adults](#)).

### Altered sexual function

1.4.8 Consider testosterone<sup>[1]</sup> supplementation for menopausal women with low sexual desire if HRT alone is not effective.

### Urogenital atrophy

1.4.9 Offer vaginal oestrogen to women with urogenital atrophy (including those on systemic HRT) and continue treatment for as long as needed to relieve symptoms.



- 1.4.10 Consider vaginal oestrogen for women with urogenital atrophy in whom systemic HRT is contraindicated, after seeking advice from a healthcare professional with expertise in menopause.
- 1.4.11 If vaginal oestrogen does not relieve symptoms of urogenital atrophy, consider increasing the dose after seeking advice from a healthcare professional with expertise in menopause.
- 1.4.12 Explain to women with urogenital atrophy that:
- symptoms often come back when treatment is stopped
  - adverse effects from vaginal oestrogen are very rare
  - they should report unscheduled vaginal bleeding to their GP.
- 1.4.13 Advise women with vaginal dryness that moisturisers and lubricants can be used alone or in addition to vaginal oestrogen.
- 1.4.14 Do not offer routine monitoring of endometrial thickness during treatment for urogenital atrophy.

### **Complementary therapies and unregulated preparations**

- 1.4.15 Explain to women that the efficacy and safety of unregulated compounded bioidentical hormones are unknown.
- 1.4.16 Explain to women who wish to try complementary therapies that the quality, purity and constituents of products may be unknown.
- 1.4.17 Advise women with a history of, or at high risk of, breast cancer that, although there is some evidence that St John's wort may be of benefit in the relief of vasomotor symptoms, there is uncertainty about:
- appropriate doses
  - persistence of effect
  - variation in the nature and potency of preparations

- potential serious interactions with other drugs (including tamoxifen, anticoagulants and anticonvulsants).

## Review and referral

- 1.4.18 Discuss with women the importance of keeping up to date with nationally recommended health screening.
- 1.4.19 Review each treatment for short-term menopausal symptoms:
- at 3 months to assess efficacy and tolerability
  - annually thereafter unless there are clinical indications for an earlier review (such as treatment ineffectiveness, side effects or adverse events).
- 1.4.20 Refer women to a healthcare professional with expertise in menopause if treatments do not improve their menopausal symptoms or they have ongoing troublesome side effects.
- 1.4.21 Consider referring women to a healthcare professional with expertise in menopause if:
- they have menopausal symptoms and contraindications to HRT or
  - there is uncertainty about the most suitable treatment options for their menopausal symptoms.

## Starting and stopping HRT

- 1.4.22 Explain to women with a uterus that unscheduled vaginal bleeding is a common side effect of HRT within the first 3 months of treatment but should be reported at the 3-month review appointment, or promptly if it occurs after the first 3 months (see recommendations on endometrial cancer in the NICE guideline on [suspected cancer](#)).
- 1.4.23 Offer women who are stopping HRT a choice of gradually reducing or immediately stopping treatment.
- 1.4.24 Explain to women that:

- gradually reducing HRT may limit recurrence of symptoms in the short term
- gradually reducing or immediately stopping HRT makes no difference to their symptoms in the longer term.

## Women with, or at high risk of, breast cancer

1.4.25 For advice on the treatment of menopausal symptoms in women with breast cancer or at high risk of breast cancer, see section 1.13 of the NICE guideline on [early and locally advanced breast cancer](#) and section 1.7 of the NICE guideline on [familial breast cancer](#).

1.4.26 Offer menopausal women with, or at high risk of, breast cancer:

- information on all available treatment options
- information that the SSRIs paroxetine and fluoxetine should not be offered to women with breast cancer who are taking tamoxifen
- referral to a healthcare professional with expertise in menopause.

## 1.5 *Long-term benefits and risks of hormone replacement therapy*

### Venous thromboembolism

1.5.1 Explain to women that:

- the risk of venous thromboembolism (VTE) is increased by oral HRT compared with baseline population risk
- the risk of VTE associated with HRT is greater for oral than transdermal preparations
- the risk associated with transdermal HRT given at standard therapeutic doses is no greater than baseline population risk.

1.5.2 Consider transdermal rather than oral HRT for menopausal women who are at increased risk of VTE, including those with a BMI over 30 kg/m<sup>2</sup>.

1.5.3 Consider referring menopausal women at high risk of VTE (for example, those with a strong family history of VTE or a hereditary thrombophilia) to a haematologist for assessment before considering HRT.

## Cardiovascular disease

1.5.4 Ensure that menopausal women and healthcare professionals involved in their care understand that HRT:

- does not increase cardiovascular disease risk when started in women aged under 60 years
- does not affect the risk of dying from cardiovascular disease.

1.5.5 Be aware that the presence of cardiovascular risk factors is not a contraindication to HRT as long as they are optimally managed.

1.5.6 Using tables 1 and 2, explain to women that:

- the baseline risk of coronary heart disease and stroke for women around menopausal age varies from one woman to another according to the presence of cardiovascular risk factors
- HRT with oestrogen alone is associated with no, or reduced, risk of coronary heart disease
- HRT with oestrogen and progestogen is associated with little or no increase in the risk of coronary heart disease.

1.5.7 Explain to women that taking oral (but not transdermal) oestrogen is associated with a small increase in the risk of stroke. Also explain that the baseline population risk of stroke in women aged under 60 years is very low (see table 2).

**Table 1 Absolute rates of coronary heart disease for different types of HRT compared with no HRT (or placebo), different durations of HRT use and time since stopping HRT for menopausal women**

|  |  |  |
|--|--|--|
|  |  | Difference in coronary heart disease incidence per 1000 menopausal women over 7.5 years (95% confidence interval) (baseline population risk in the UK over 7.5 years: 26.3 per 1000 <sup>1</sup> ) |
|--|--|--|

|                                  |                                     | Current HRT users  | Treatment duration <5 years | Treatment duration 5–10 years | >5 years since stopping treatment |
|----------------------------------|-------------------------------------|--------------------|-----------------------------|-------------------------------|-----------------------------------|
| Women on oestrogen alone         | RCT estimate <sup>2</sup>           | 6 fewer (-10 to 1) | No available data           | No available data             | 6 fewer (-9 to -2)                |
|                                  | Observational estimate <sup>3</sup> | 6 fewer (-9 to -3) | No available data           | No available data             | No available data                 |
| Women on oestrogen + progestogen | RCT estimate <sup>2</sup>           | 5 more (-3 to 18)  | No available data           | No available data             | 4 more (-1 to 11)                 |
|                                  | Observational estimate <sup>3</sup> | No available data  | No available data           | No available data             | No available data                 |

HRT, hormone replacement therapy; RCT, randomised controlled trial

For full source references, see Appendix M in the [full guideline](#).

<sup>1</sup> Results from Weiner 2008 were used for the baseline population risk estimation.

<sup>2</sup> For women aged 50–59 years at entry to the RCT.

<sup>3</sup> Observational estimates are based on cohort studies with several thousand women.

**Table 2 Absolute rates of stroke for different types of HRT compared with no HRT (or placebo), different durations of HRT use and time since stopping HRT for menopausal women**

|                          |                                     | Difference in stroke incidence per 1000 menopausal women over 7.5 years (95% confidence interval) (baseline population risk in the UK over 7.5 years: 11.3 per 1000 <sup>1</sup> ) |                             |                               |                                   |
|--------------------------|-------------------------------------|--|-----------------------------|-------------------------------|-----------------------------------|
|                          |                                     | Current HRT users  | Treatment duration <5 years | Treatment duration 5–10 years | >5 years since stopping treatment |
| Women on oestrogen alone | RCT estimate <sup>2</sup>           | 0 (-5 to 10)   | No available data           | No available data             | 1 more (-4 to 9)                  |
|                          | Observational estimate <sup>3</sup> | 3 more (-1 to 8)   | No available data           | No available data             | No available data                 |

|                                  |                                     |                   |                   |                   |                   |
|----------------------------------|-------------------------------------|-------------------|-------------------|-------------------|-------------------|
| Women on oestrogen + progestogen | RCT estimate <sup>2</sup>           | 6 more (-2 to 21) | No available data | No available data | 4 more (-1 to 13) |
|                                  | Observational estimate <sup>3</sup> | 4 more (1 to 7)   | No available data | No available data | No available data |

HRT, hormone replacement therapy; RCT, randomised controlled trial  
For full source references, see Appendix M in the [full guideline](#).

<sup>1</sup> Results from Weiner 2008 were used for the baseline population risk estimation.

<sup>2</sup> For women aged 50–59 years at entry to the RCT.

<sup>3</sup> Observational estimates are based on cohort studies with several thousand women.

## Type 2 diabetes

- 1.5.8 Explain to women that taking HRT (either orally or transdermally) is not associated with an increased risk of developing type 2 diabetes.
- 1.5.9 Ensure that women with type 2 diabetes and all healthcare professionals involved in their care are aware that HRT is not generally associated with an adverse effect on blood glucose control.
- 1.5.10 Consider HRT for menopausal symptoms in women with type 2 diabetes after taking comorbidities into account and seeking specialist advice if needed.

## Breast cancer

- 1.5.11 Using table 3, explain to women around the age of natural menopause that:
- the baseline risk of breast cancer for women around menopausal age varies from one woman to another according to the presence of underlying risk factors
  - HRT with oestrogen alone is associated with little or no change in the risk of breast cancer
  - HRT with oestrogen and progestogen can be associated with an increase in the risk of breast cancer
  - any increase in the risk of breast cancer is related to treatment duration and reduces after stopping HRT.

**Table 3 Absolute rates of breast cancer for different types of HRT compared with no HRT (or placebo), different durations of HRT use and time since stopping HRT for menopausal women**

|                                  |                                     | Difference in breast cancer incidence per 1000 menopausal women over 7.5 years (95% confidence interval) (baseline population risk in the UK over 7.5 years: 22.48 per 1000 <sup>1</sup> ) |                             |                               |                                   |
|----------------------------------|-------------------------------------|--|-----------------------------|-------------------------------|-----------------------------------|
|                                  |                                     | Current HRT users  | Treatment duration <5 years | Treatment duration 5–10 years | >5 years since stopping treatment |
| Women on oestrogen alone         | RCT estimate <sup>2</sup>           | 4 fewer (-11 to 8)   | No available data           | No available data             | 5 fewer (-11 to 2)                |
|                                  | Observational estimate <sup>3</sup> | 6 more (1 to 12) <sup>4</sup>  | 4 more (1 to 9)             | 5 more (-1 to 14)             | 5 fewer (-9 to -1)                |
| Women on oestrogen + progestogen | RCT estimate <sup>2</sup>           | 5 more (-4 to 36)  | No available data           | No available data             | 8 more (1 to 17)                  |
|                                  | Observational estimate <sup>3</sup> | 17 more (14 to 20)   | 12 more (6 to 19)           | 21 more (9 to 37)             | 9 fewer (-16 to 13) <sup>5</sup>  |

HRT, hormone replacement therapy; RCT, randomised controlled trial

For full source references, see Appendix M in the [full guideline](#).

<sup>1</sup> Office for National Statistics (2010) [breast cancer incidence statistics](#).

<sup>2</sup> For women aged 50–59 years at entry to the RCT.

<sup>3</sup> Observational estimates are based on cohort studies with several thousand women.

<sup>4</sup> Evidence on observational estimate demonstrated very serious heterogeneity without plausible explanation by subgroup analysis.

<sup>5</sup> Evidence on observational estimate demonstrated very serious imprecision in the estimate of effect.

## Osteoporosis

- 1.5.12 Give women advice on bone health and discuss these issues at review appointments (see the NICE guideline on [osteoporosis: assessing the risk of fragility fracture](#)).

- 1.5.13 Using table 4, explain to women that the baseline population risk of fragility fracture for women around menopausal age in the UK is low and varies from one woman to another.
- 1.5.14 Using table 4, explain to women that their risk of fragility fracture is decreased while taking HRT and that this benefit:
- is maintained during treatment but decreases once treatment stops
  - may continue for longer in women who take HRT for longer.

**Table 4 Absolute rates of any fragility fracture for HRT compared with no HRT (or placebo), different durations of HRT use and time since stopping HRT for menopausal women**

|                  |                                     | Difference in any fragility fracture incidence per 1000 menopausal women (95% confidence interval) (see footnotes for information on baseline population risk and length of follow-up time over which absolute risk difference is calculated) |                                    |                                    |                                   |
|------------------|-------------------------------------|---|------------------------------------|------------------------------------|-----------------------------------|
|                  |                                     | Current HRT users   | Treatment duration <5 years        | Treatment duration 5–10 years      | >5 years since stopping treatment |
| Women on any HRT | RCT estimate <sup>1</sup>           | 23 fewer (-10 to -33) <sup>3</sup>  | 25 fewer (-9 to -37) <sup>4</sup>  | No available data                  | No available data                 |
|                  | Observational estimate <sup>2</sup> | 16 fewer (-15 to -18) <sup>5</sup>  | 15 fewer (-11 to -17) <sup>5</sup> | 18 fewer (-15 to -20) <sup>5</sup> | 2 more (-19 to 27) <sup>6</sup>   |



HRT, hormone replacement therapy; RCT, randomised controlled trial

For full source references, see Appendix M in the [full guideline](#).

Absolute risks calculated by using the baseline population risk in the control arm for each analysis, following GRADE methodology.

<sup>1</sup> For women aged 50–59 years at entry to the RCT.

<sup>2</sup> Observational estimate is based on cohort studies with several thousand women.

<sup>3</sup> Baseline population risk = 69 per 1000 women (follow-up: 3.43 years).

<sup>4</sup> Baseline population risk = 78 per 1000 women (follow-up: 3.71 years).

<sup>5</sup> Baseline population risk = 15.4 per 1000 women (follow-up: 2.8 years).

<sup>6</sup> Baseline population risk = 106 per 1000 women (follow-up: 5 years).

## Dementia

- 1.5.15 Explain to menopausal women that the likelihood of HRT affecting their risk of dementia is unknown.

## Loss of muscle mass and strength

- 1.5.16 Explain to women that:

- there is limited evidence suggesting that HRT may improve muscle mass and strength
- muscle mass and strength is maintained through, and is important for, activities of daily living.

## 1.6 *Diagnosing and managing premature ovarian insufficiency*

### Diagnosing premature ovarian insufficiency

- 1.6.1 Take into account the woman's clinical history (for example, previous medical or surgical treatment) and family history when diagnosing premature ovarian insufficiency.

- 1.6.2 Diagnose premature ovarian insufficiency in women aged under 40 years based on:

- menopausal symptoms, including no or infrequent periods (taking into account whether the woman has a uterus) and

- elevated FSH levels on 2 blood samples taken 4–6 weeks apart.
- 1.6.3 Do not diagnose premature ovarian insufficiency on the basis of a single blood test.
- 1.6.4 Do not routinely use anti-Müllerian hormone testing to diagnose premature ovarian insufficiency.
- 1.6.5 If there is doubt about the diagnosis of premature ovarian insufficiency, refer the woman to a specialist with expertise in menopause or reproductive medicine.

### Managing premature ovarian insufficiency

- 1.6.6 Offer sex steroid replacement with a choice of HRT or a combined hormonal contraceptive to women with premature ovarian insufficiency, unless contraindicated (for example, in women with hormone-sensitive cancer).
- 1.6.7 Explain to women with premature ovarian insufficiency:
- the importance of starting hormonal treatment either with HRT or a combined hormonal contraceptive and continuing treatment until at least the age of natural menopause (unless contraindicated)
  - that the baseline population risk of diseases such as breast cancer and cardiovascular disease increases with age and is very low in women aged under 40
  - that HRT may have a beneficial effect on blood pressure when compared with a combined oral contraceptive
  - that both HRT and combined oral contraceptives offer bone protection
  - that HRT is not a contraceptive.
- 1.6.8 Give women with premature ovarian insufficiency and contraindications to hormonal treatments advice, including on bone and cardiovascular health, and symptom management.

- 1.6.9 Consider referring women with premature ovarian insufficiency to healthcare professionals who have the relevant experience to help them manage all aspects of physical and psychosocial health related to their condition.

### *Terms used in this guideline*

**Compounded bioidentical hormones** Unregulated plant-derived hormonal combinations similar or identical to human hormones that are compounded by pharmacies to the specification of the prescriber.

**Fragility fracture** Fractures that result from mechanical forces that would not ordinarily result in fracture (such as a fall from a standing height or less). Reduced bone density is a major risk factor for fragility fractures, which occur most commonly in the spine, hip and wrist.

**Low mood** Mild depressive symptoms that impair quality of life but are usually intermittent and often associated with hormonal fluctuations in perimenopause.

**Menopause** A biological stage in a woman's life that occurs when she stops menstruating and reaches the end of her natural reproductive life. Usually it is defined as having occurred when a woman has not had a period for 12 consecutive months (for women reaching menopause naturally). The changes associated with menopause occur when the ovaries stop maturing eggs and secreting oestrogen and progesterone.

**Menopausal women** This includes women in perimenopause and postmenopause.

**Perimenopause** The time in which a woman has irregular cycles of ovulation and menstruation leading up to menopause and continuing until 12 months after her final period. The perimenopause is also known as the menopausal transition or climacteric.

**Postmenopause** The time after menopause has occurred, starting when a woman has not had a period for 12 consecutive months.

**Premature ovarian insufficiency** Menopause occurring before the age of 40 years (also known as premature ovarian failure or premature menopause). It can occur naturally or as a result of medical or surgical treatment.

**Urogenital atrophy** Thinning and shrinking of the tissues of the vulva, vagina, urethra and bladder caused by oestrogen deficiency. This results in multiple symptoms such as vaginal dryness, vaginal irritation, a frequent need to urinate and urinary tract infections.

**Vasomotor symptoms** Menopausal symptoms such as hot flushes and night sweats caused by constriction and dilatation of blood vessels in the skin that can lead to a sudden increase in blood flow to allow heat loss. These symptoms can have a major impact on activities of daily living.

You can also see this guideline in the NICE pathway on [menopause](#).

To find out what NICE has said on topics related to this guideline, see our web page on [menopause](#).

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<sup>[1]</sup> At the time of publication (November 2015), testosterone did not have a UK marketing authorisation for this indication in women. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Prescribing guidance: prescribing unlicensed medicines](#) for further information.

## Menopause implementation: getting started

This section highlights 3 areas of the menopause guideline that could have a big impact on practice and be challenging to implement, along with the reasons why we are proposing change in these areas (given in the box at the start of each area). We identified these with the help of stakeholders and Guideline Development Group members (see [section 9.4 of the manual](#)). The section also gives information on resources to help with implementation.

### *The challenge: stopping the use of follicle-stimulating hormone tests to diagnose menopause in women aged over 45 years*

See recommendation 1.2.5.

The follicle-stimulating hormone (FSH) test is often performed unnecessarily in women aged over 45 years. The evidence underpinning this guideline highlights that hormonal tests should not routinely be used in the diagnosis of menopause and that FSH tests should not be used in women aged over 45 years. This is because FSH fluctuates considerably over short periods of time during the years leading up to menopause and so blood levels are not a helpful addition to what is a clinical diagnosis. If a woman is aged over 45 years and has not had a period for at least 12 months, or has vasomotor symptoms and irregular periods (or just symptoms if she doesn't have a uterus), this is adequate information to diagnose menopause and perimenopause respectively. In younger women, FSH tests should not be used to diagnose menopause in those taking combined oestrogen and progestogen contraception or high-dose progestogen because these affect FSH measurements.

Carrying out this test in this group of women does not improve menopause management and so this is an area of care where considerable savings could be made through disinvestment.

### Raising awareness of the need to change practice

There may be staff in primary care services who do not know that FSH tests should not be carried out in women aged over 45 years.

To raise awareness, clinical commissioning groups, practice managers and lead GPs could:

- Use newsletters, bulletins and education events to help ensure that GPs and other practice staff (in particular practice nurses) are aware of this change in practice and that they understand the evidence underpinning this recommendation.

- Add a prompt to electronic requesting systems which remind primary care staff that this test should not be requested for women aged over 45.
- Refer GPs to NICE's [clinical knowledge summary](#) for menopause.
- Use the NICE [costing report and template](#) to estimate the local savings that can be made. A sample calculation using this template showed that savings of £16,500 could be made for a population of 100,000.
- Use the [baseline assessment tool](#) to establish current practice in requesting tests and carry out clinical audit so this can be monitored and improved.

Also, laboratory staff and managers could:

- Engage with their local GP practices. For example, in NHS Lothian a GP/laboratory liaison group meets regularly every 2 months and holds an annual update meeting to which all GPs are invited. This continuing professional development (CPD) accredited meeting provides a good opportunity to promote changes in practice.
- Encourage GPs to stop requesting FSH tests for women aged over 45 years by drawing attention to the fact that this test is unlikely to be informative and is not recommended. [Lab Tests Online UK](#) and the UK National External Quality Assessment Service (UK [NEQAS](#)) are also raising awareness of the new NICE guidance.

### *The challenge: communicating the long-term benefits and risks of hormone replacement therapy*

See section 1.5.

It is important to provide information on the benefits and risks of hormone replacement therapy (HRT) to help women make an informed choice about which treatment to use for menopausal symptoms. Media reports about HRT have not always been accurate, so providing healthcare professionals and women with a robust source of information is vital. Before publication of this guideline there was no consensus about the long-term benefits and risks of HRT. Although the [Women's Health Initiative](#) found that HRT prevented osteoporotic fractures and colon cancer, it initially reported that HRT increased the risk of having a cardiovascular event as well as the incidence of breast cancer. However, the association between HRT and cardiovascular disease has since been disputed and the results show that the risk varies in accordance with individual factors. One of the aims of this guideline is to help GPs and other healthcare professionals to be more confident in prescribing HRT and women more confident in taking it. A knowledge gap among some GPs and other healthcare professionals could mean that they are reluctant to prescribe HRT because they overestimate the risks and contraindications, and underestimate the impact of menopausal symptoms on a woman's quality of life.

## Improving knowledge among healthcare professionals

There is a need to improve knowledge about the long-term benefits and risks of HRT. No other treatment has been shown to be as effective as HRT for menopausal symptoms, though the balance of risks and benefits varies among women. Healthcare professionals need to be in a position to be able to support women to make an informed decision about individual benefits and risks of HRT.

NICE is working with the Royal College of Obstetricians and Gynaecologists to ensure that management of menopause, including the benefits and risks of HRT, is covered within the [core curriculum](#). This includes supporting the update and promotion of the [advanced training specialist module](#) on menopause and the [subspecialty training in reproductive medicine](#). We are also working with the Faculty of Sexual & Reproductive Healthcare (FSRH) to highlight the [menopause special skills theory course](#) and the basic and advanced [special skills module](#).

To improve knowledge, clinical commissioning group prescribing leads could:

- Help to develop formularies of good HRT prescribing for GPs. This could be done with input from GPs with a specialist interest in menopause and interested consultant gynaecologists.
- Use briefings and newsletters to help disseminate prescribing knowledge on HRT.

Also, GPs could:

- Set up local meetings or teaching sessions (particularly those GPs with a specialist interest) to target interested GPs in each practice who can then take the information back to their partners.
- Use the recommendations in [section 1.5](#) of the guideline and the HRT section of NICE's [clinical knowledge summary](#) to ensure that they are informed of the actual long-term benefits and risks of HRT for each individual and are not basing decisions on perceived knowledge.
- Use materials such as NICE's [information for the public](#), [NHS choices](#) and the [Women's Health Concern leaflet](#) to help support women to make informed decisions when advising them about HRT.
- Link with the menopause specialist in their area for advice. This could be by telephone or email about specific cases and/or through training delivered by the menopause specialist.
- Complete the basic or advanced [FSRH special skills course](#). Practice nurses may also complete this training.

### *The challenge: providing enough specialist services*

See guideline recommendations.

The number of women aged over 45 years in the UK has been steadily increasing and will continue to rise. The associated increase in the number of women going through menopause is expected to result in more new referrals to secondary care of both women needing short-term symptom control and those with associated long-term health issues. There is currently a lack of specialist services and their availability varies nationally. Throughout this guideline there are recommendations to refer certain women to a healthcare professional with expertise in menopause. Currently, there may not be enough services nationally to refer these women to.

### **Reviewing and redesigning local service provision**

In order to address variation and potential gaps in service provision, local health services may need to review, map and redesign local service provision.

To do this, commissioners and clinical commissioning groups could:

- Use Menopause UK's national [menopause map](#) as a starting point. This highlights variations in practice and the lack of overall provision.



- Clarify current referral routes and communicate them if they are effective.
- Identify lead clinicians to drive a change in service provision if a gap is identified. Ideally all clinical commissioning groups should have a GP with a specialist interest or a community gynaecologist who could do this.
- Establish whether current referrals are appropriate. These may be to secondary care (hospitals), community services or a GP with a specialist interest and will vary according to local facilities. Ideally, services should be provided by a dedicated menopause clinic.
- Confirm that care is provided by a healthcare professional with expertise in menopause (for example, women with breast cancer should have access to a specialist menopause clinic or professional but often receive treatment for menopause from their oncologist who may not have the appropriate training).
- Consider the feasibility of providing dedicated menopause support by setting up clinics within current gynaecology services.
- Menopause clinics may be multispecialist and so jointly led by a nurse consultant and a consultant ensuring that when a member of staff is unavailable the clinic may still run.
- Establish regional menopause clinics if services are unable to have their own.
- Use the learning from examples of practice where successful services have been set up to help. For example, a primary care service in Essex manages specialist clinic waiting lists through an established agreement whereby a GP with specialist interest accepts emails or written requests from all GPs within a clinical commissioning group. These requests are answered once a week. A specialist service in London has set up a helpline that receives calls outside of clinic times and can allow women to be given support and advice without the need for a clinic appointment.

### *Need more help?*

Further [resources](#) are available from NICE that may help to support implementation:

- [uptake data](#) about guideline recommendations and quality standard measures
- [the British Menopause Society](#) provides information to healthcare professionals about menopause.

## Context

Menopause is when a woman stops having periods as she reaches the end of her natural reproductive life. This is not usually abrupt, but a gradual process during which women experience perimenopause before reaching postmenopause. The average age of menopause in the UK is 51. However, this varies widely and 1 in 100 women experience premature ovarian insufficiency (menopause occurring before the age of 40 years).

Oestrogen depletion associated with menopause causes irregular periods and has many other effects on the body. The most common symptoms are hot flushes and night sweats. Other symptoms include mood changes, memory and concentration loss, vaginal dryness, a lack of interest in sex, headaches, and joint and muscle stiffness. Quality of life may be severely affected.

Most women (8 out of 10) experience some symptoms, typically lasting about 4 years after the last period, but continuing for up to 12 years in about 10% of women. Prolonged lack of oestrogen affects the bones and cardiovascular system and postmenopausal women are at increased risk of a number of long-term conditions, such as osteoporosis.

Around a million women in the UK use treatment for their menopausal symptoms. The advice and support available is variable, and use of hormone replacement therapy (HRT) – a highly successful treatment for common symptoms of menopause – varies with socioeconomic and cultural factors. The number of prescriptions for HRT almost halved after the publication of 2 large studies: the Women's Health Initiative (2002) and the Million Women Study (2003). These studies focused on the use of HRT in chronic disease prevention and potential long-term risks rather than considering the benefits in terms of symptom relief. One of the aims of this NICE guideline was to clarify the balance of benefits and risks of HRT<sup>[2]</sup> use for both women and their healthcare providers.

This guideline addresses the diagnosis and management of menopause. It covers women in perimenopause and postmenopause, and the particular needs of women with premature ovarian insufficiency and women with hormone-sensitive cancer (for example, breast cancer). The guideline concentrates on the clinical management of menopause-related symptoms, considers both pharmaceutical and non-pharmaceutical treatments, includes a health economic analysis, and reviews the benefits and adverse effects of HRT. It applies to all settings in which NHS services are provided.

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<sup>[2]</sup> At the time of publication (November 2015), the MHRA is 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 HRT products. The current core SPC

states that long-term use of oestrogen-only and combined oestrogen-progestogen HRT has been associated with a slightly increased risk of ovarian cancer.

## Recommendations for research

The Guideline Development Group has made the following recommendations for research. The full set of research recommendations is detailed in the [full guideline](#).

### *1 Women with breast cancer*

What is the safety and effectiveness of alternatives to systemic HRT as treatments for menopausal symptoms in women who have had treatment for breast cancer?

#### **Why this is important**

Women with a history of breast cancer are rarely offered hormonal treatment for menopausal symptoms but the available alternatives are less effective. There is limited evidence from randomised controlled trials on the safety and effectiveness of options such as non-hormonal treatments, ospemifene, conjugated equine estrogen/bazedoxifene (CEE/BZA) or local vaginal oestrogen for menopausal symptoms in women who have had treatment for breast cancer. There is insufficient evidence on the efficacy and safety of non-pharmaceutical treatments in women with breast cancer and other hormone-sensitive conditions. Randomised controlled trials or large cohort studies are needed to understand the effects of these treatments in women with breast cancer, and to investigate if there is a difference in breast cancer recurrence, mortality and tumour aggression with different types of treatment.

### *2 Effects of HRT on breast cancer risk*

What is the difference in the risk of breast cancer in menopausal women on HRT with progesterone, progestogen or selective oestrogen receptor modulators?

#### **Why this is important**

Fear of breast cancer deters many women from taking HRT, even in the presence of debilitating menopausal symptoms. There is a lack of evidence from randomised controlled trials directly comparing the risk of breast cancer in menopausal women on HRT with progesterone, progestogen or selective oestrogen receptor modulators. There is a need for a national registry of women with breast cancer.

Optimising the risk–benefit profile of HRT will potentially reduce morbidity and mortality from breast cancer in women who need HRT over the long term because of continuing menopausal symptoms.

### *3 Effects of HRT on venous thromboembolism risk*

How does the preparation of HRT affect the risk of venous thromboembolism (VTE)?

#### **Why this is important**

An increase in the risk of VTE (deep vein thrombosis [DVT] or pulmonary embolism [PE]) is a significant side effect of HRT, particularly because PEs can be fatal. This risk appears to be greater with oral than transdermal HRT. DVT risk increases with age and BMI, among other risk factors.

The progestogen component of HRT may also influence the risk of a DVT, which may be greater with androgenic synthetic progestogens than natural progesterone (but findings from observational studies need confirmation). Most women in the UK take oral HRT comprising oestrogen combined with a synthetic progestogen, and the use of progesterone is less common.

Randomised controlled trials are needed to compare oral with transdermal HRT, and HRT containing different types of progestogens. These trials should measure coagulation factors and the incidence of VTE in women at increased risk of VTE for whom transdermal oestrogen is indicated.

### *4 Effects of HRT on dementia risk*

What are the effects of early HRT use on the risk of dementia?

#### **Why this is important**

Concern about the prospect of dementia in older age is increasing and any beneficial effect on the future risk of dementia will be important to women who are considering using HRT. There is a need for good-quality observational studies controlling for the effect of important confounders on how early HRT use affects dementia risk in women with early natural menopause, including women with premature ovarian insufficiency.

## 5 *Premature ovarian insufficiency*

What are the main clinical manifestations of premature ovarian insufficiency and the short- and long-term impact of the most common therapeutic interventions?

### Why this is important

Women with premature ovarian insufficiency can experience the effects of menopause for most of their adult life. This can lead to reduced quality of life and an increased risk of osteoporosis, cardiovascular disease and possibly dementia. There is uncertainty about the diagnosis, time course and management of premature ovarian insufficiency. For example, it is possible that different interventions produce different outcomes in terms of quality of life, and bone, cardiovascular and brain protection. Combined oral contraceptives are often prescribed when this might not be the best treatment in terms of quality of life and preservation of bone density and cardiovascular health. Short- and long-term outcomes of HRT versus combined hormonal contraceptives in women with premature ovarian insufficiency therefore need to be investigated.

Development of a collaborative premature ovarian insufficiency registry would allow the collection of high-quality demographic, biobank (genomic) and clinical data in order to clarify:

- the diagnosis and presentation of premature ovarian insufficiency
- the impact of therapeutic interventions such as combined hormonal contraceptives, HRT and androgens
- the long-term impact of premature ovarian insufficiency on bone density and fracture, and cardiovascular and cognitive health
- the long-term risk of cancer, which can be determined by linking with relevant cancer and mortality registries.

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## Accreditation

