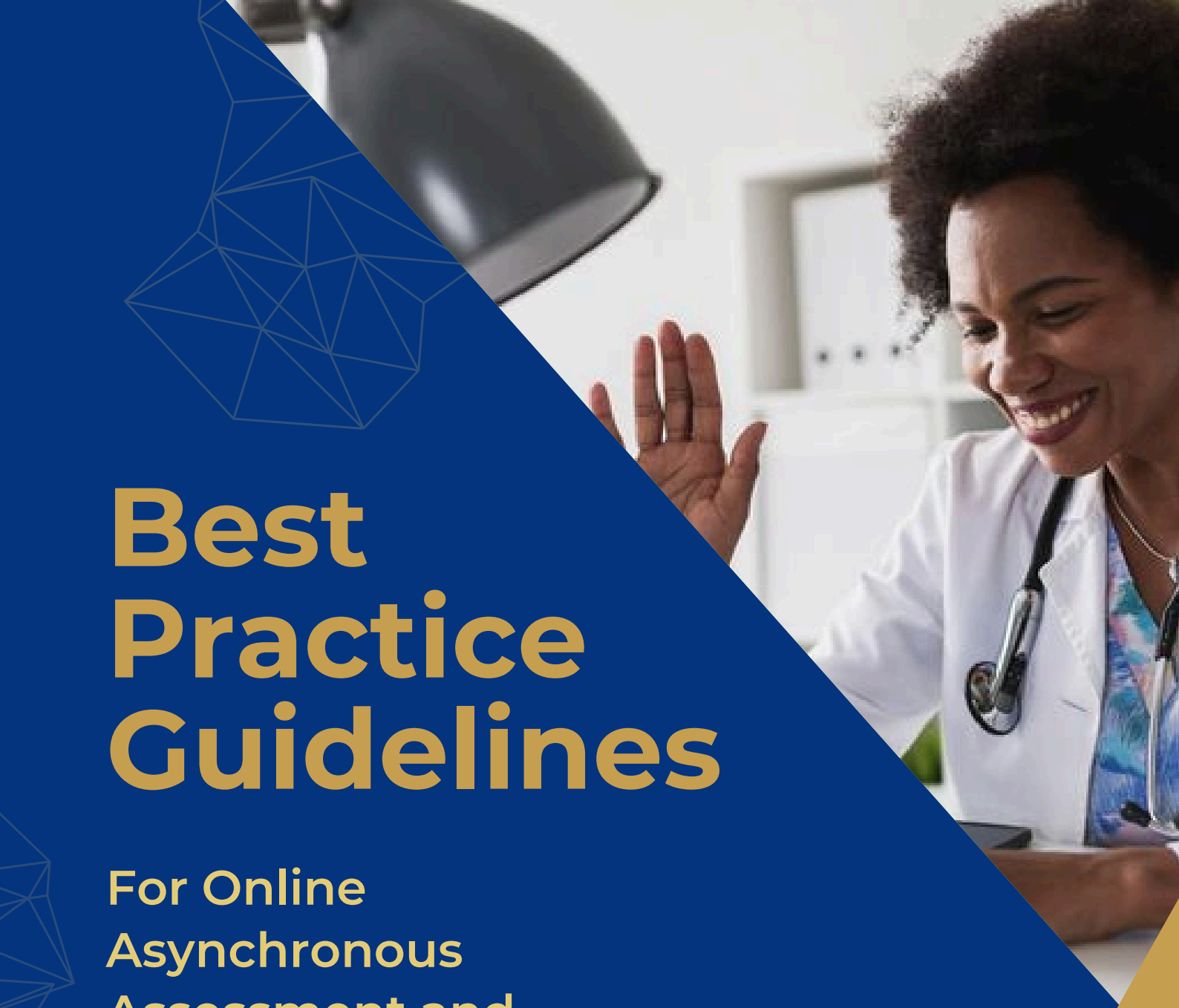

Best Practice Guidelines

For Online Asynchronous Assessment and Follow-up for Women Initiating Hormone Replacement Therapy

DiCE

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About this document

These Best Practice Guidlines (BPGs) are based on the collective experience of established online healthcare providers who participate in the Digital Clinical Excellence (DiCE) Forum. Working group virtual meetings were held between January and April 2024. The purpose of these meetings was to gather and review existing evidence and contemporary practices, and to form a consensus on a best practice approach to enhance the quality and safety of online / remote prescribing within the independent pharmacy sector.

DiCE BPG aims to align with existing professional and regulatory standards, but also to broaden and strengthen them from an industry perspective. This is in recognition of the fact that rapidly progressing and expanding areas of care are often developing at a faster pace than professional or regulatory standards are published. BPGs are not intended to replace or contest any current professional or regulatory standards. Prescribers must always adhere to the standards set by regulatory bodies relevant to their profession, and any other relevant national guidance.

DiCE BPG applies only to prescribers and is not intended for use by healthcare practitioners operating under a Patient Group Direction. In addition, while DiCE BPG may be useful for prescribers operating outside of the United Kingdom, it is not written with this purpose in mind and some recommendations may not apply.

The recommendations made in this guidance consider the risks and responsibilities of prescribing HRT to women for the first time. Prescribing decisions must be made based on a comprehensive assessment of the patient's individual medical and other needs, which may be complex. Repeat prescribing does not carry the same risks and responsibilities as initial prescribing.

For the purposes of this guidance, the term 'HRT' refers to oestrogen-containing medicines (with or without progesterone) only. Testosterone is not currently licensed to treat the symptoms of menopause and therefore falls outside the scope of this guidance. Recommendations are regularly reviewed and updated where necessary.

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Digital Clinical Excellence 'DiCE'

DiCE Best Practice Guidelines are not intended to replace current prescribing information. Prescribers should always refer to the BNF and Summary of Product Characteristics, and any relevant national guidelines

About Digital Clinical Excellence 'DiCE'

DiCE was established in March 2019 to provide a collective voice and support to the growing community of UK digital healthcare providers. The network aims to drive excellence in digital care standards to support clinical care improvement and safety in digital healthcare. DiCE members are senior clinical leaders from online clinical service providers who ensure collective governance for DiCE. There is no commercial focus or activity within the network.

DiCE aims to work collaboratively within the industry and with relevant professional bodies and healthcare regulators to produce its Best Practice Guidance. However, these are industry produced and should not be regarded as being endorsed by any professional body or regulator, who have their own standards. Healthcare professionals are reminded that the only statutory standards that must be adhered to are those produced by the UK healthcare regulators. Established national guidance such as those produced by NICE, SIGN or other statutory bodies must also be followed.

DiCE is managed by Healthworks Ventures Ltd.

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About digital asynchronous prescribing

The term 'digital asynchronous prescribing' describes the process of online / remote prescribing of medicines using a form-based assessment, without a real-time conversation between prescriber and patient.

Digital asynchronous prescribing is subject to the same legal requirements and regulations as in-office primary care, including the Royal Pharmaceutical Society (RPS) competency framework for consultations and prescribing governance that applies to all prescribers in England and Wales [1].

In addition, registered online pharmacies and other prescribing platforms are required to follow guidance and professional standards set by relevant regulatory bodies, for example the General Medical Council (GMC) and the General Pharmaceutical Council (GPhC) [2-4]. In England, registered prescribing platforms employing doctors as part of the prescribing team also fall under the remit of the Care Quality Commission (CQC) [5].

When conducted in a well-regulated setting with good risk management systems, routine reviews to drive continuous learning improvement, and careful consideration of how information is provided to patients, asynchronous prescribing can be effective in replacing some in-office primary care visits, providing timely care and increased convenience for patients [6–11].

For more general information on professional standards and guidance relevant to digital asynchronous prescribing, refer to the following documents developed by UK regulatory and professional bodies:

- Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet (GPhC, 2022) [12]
- Good practice in prescribing and managing medicines and devices (GMC, 2021) [4]
- Policy for providing medicines online (RPS, 2019) [13]
- Is a remote consultation appropriate? (GMC, 2019) [14]
- Remote prescribing high-level principles (Joint statement by UK-wide healthcare regulators, royal colleges and faculties, 2019) [15]
- The state of care in independent online primary health services (CQC, 2018) [5]

1. Hormone Replacement Therapy

Menopause is a natural process that typically affects women between the ages of 45 and 55 years, characterised by a gradual decline in oestrogen levels and cessation of menstruation [16,17].

Some women go through early menopause, before the age of 45. This may occur naturally, or it may occur as a result of cancer treatment (e.g. chemotherapy or radiotherapy to the pelvis) or removal of the ovaries surgically [18]. Rarely, menopause can occur in women under 40 years of age as a result of primary ovarian insufficiency (POI) [19,20].

Symptoms associated with menopause include, but are not limited to [16,19,21,22]:

- Hot flushes, which may be accompanied by heart palpitations
- Mood swings, irritability, and impaired ability to concentrate on or remember things
- Feeling very emotional or anxious
- Night sweats and difficulty sleeping
- Loss of interest in sex, which may cause emotional distress
- Vaginal dryness and discomfort, which can lead to painful sex
- Bladder symptoms (e.g. needing to pass urine more often and/or more urgently, increased risk of urinary tract infections), which tend to worsen over time without treatment

Women who experience early menopause due to cancer treatment or surgery experience a rapid decline in their oestrogen, progesterone and testosterone levels. This may cause them to experience the symptoms of menopause more intensely than women going through the menopause naturally [23].

Hormone replacement therapy (HRT) aims to replace the hormones no longer being produced by the ovaries of peri- and post-menopausal women, thereby relieving the symptoms of menopause [24].

Decades of evidence support the use of HRT to [22,25,26]:

- Help with vasomotor symptoms (e.g. hot flushes and night sweats)
- Prevent vaginal dryness and discomfort
- Prevent loss of bone density
- Help maintain a healthy heart
- Prevent cognitive decline in later life.

HRT may be prescribed for a short time or for many years [22,27]. The duration of treatment is determined by the patient's personal preference and discussions of the risk vs. benefits of continuing therapy.

1.1 Treatment regimens

If a woman still has her uterus, the endometrium (womb lining) must be protected with progesterone [28]. Women who have had a hysterectomy can be treated with oestrogen alone, unless the hysterectomy was performed for significant endometriosis [28].

Women who had their last period more than 1 year ago may be suited to continuous combined therapy, whereas those who are still peri-menopausal will require a cyclical regimen (also known as sequential HRT) for approximately a further year [29,30].

Required doses of HRT vary between each person, and currently licensed HRT products in the UK include systemic (oral tablets, skin patches, gels, and sprays) [24] and local treatment for bladder and vaginal problems (rings, tablets, pessaries, gels and creams) [31,32]. The range of HRT medicines availability may vary by provider.

The risk of some side effects (e.g. blood clots) are higher with oral therapy than with transdermal HRT medicines, though the overall risk is still small [33]. Women should be assessed for risk factors for thromboembolic disease before prescribing [22, 34].

Women with a history of migraine should be treated transdermally rather than with oral therapy, to reduce the potential for hormone fluctuations that can trigger headache and migraine [35].

1.2 Lifestyle changes for long-term health

Although HRT can help to prevent bone density loss and reduce future risk of heart disease in peri-menopausal women, patients should be encouraged to take additional steps to protect their long-term health [22,27].

These include giving up smoking, drinking alcohol in moderation, following a healthy balanced diet, maintaining a daily calcium intake of around 700 mg, and doing regular moderate weight-bearing and aerobic exercise [36].

2. Why is a best practice approach needed?

2.1 Providing a safe and trustworthy service

The demand for HRT is currently at an all-time high. Recently published NHS data show that 2.3 million patients in England were prescribed HRT in 2022-23 compared with 1.8 million in 2021-22, and a 47% increase in the number of HRT items prescribed (from 7.4 million to 10.9 million) [37].

HRT treatment is a complex area and requires careful consideration of all the needs of a menopausal patient [19,22]. This should include past medical, obstetric, gynaecological and mental health history (see Section 4.2). Establishing a best practice approach is essential to reassure patients that their medication is coming from trustworthy pharmacies and clinicians who are aware of any risks and clear on their responsibility to protect patients.

Online prescribers have a duty to provide a safe service for all patients seeking HRT, and to follow the professional standards set by the regulatory body relevant to their profession [2–4]. For example, the GMC professional standards state that medicines should only be prescribed if the prescriber feels that they have adequate knowledge of the patient's health, and are satisfied that the medicines serve the patient's needs [4]. These principles are closely aligned with those of the GPhC [3].

It is expected that all prescribers using asynchronous form-based assessments have undertaken a comprehensive risk assessment of the service being provided, in line with current statutory guidance and standards [2,4,12].

If the prescriber feels that a patient's asynchronous form-based assessment does not provide sufficient information to make a safe prescribing decision, and further information is required from the patient, it may be that a telephone or video consultation (or other two-way communication method) is needed. If the prescriber feels that additional sources of information are needed to make a safe prescribing decision, they may ask the patient (or another healthcare professional involved in their care – see section 2.2) to provide this information. Examples of potentially useful documents include recent hospital discharge letters, test results and clinic letters.

Best practice in digital asynchronous prescribing requires that appropriate screening, prescribing and monitoring is undertaken by professionals meeting the requirements of the RPS competency framework [1]. To ensure high-quality provision of care, online prescribers should proactively audit and review the quality and safety of their menopause service. This includes analysing prescribing trends to be able to identify any inappropriate prescribing and supply.

In addition, consideration should be given to providing pharmacy teams with training on HRT medicines, as well as pharmacists having access to a prescriber of appropriate seniority who can provide further advice and support.

2.2 Information sharing and patient consent

Current professional and regulatory standards recommend that online prescribers request patient consent to share their treatment details with their other healthcare professionals involved in their care (for example, their GP) before prescribing prescription-only medicines [2,4].

Patients wishing to initiate HRT via asynchronous form-based assessment should be asked to consent to GP notification. If a patient refuses consent, the prescriber should record their reasons for refusing (for example, concerns about privacy). They should also inform the patient about the importance of sharing information between healthcare providers to ensure continuity of care, and the potential risks of not sharing this information.

Prescribers should keep a clear written record of treatment decisions made based on the information provided by the patient, particularly if HRT is prescribed without obtaining consent for GP notification. This is in line with current professional and regulatory standards [2,4].

In cases where failing to share information could pose a risk to patient safety, the prescriber should inform the patient that they cannot prescribe and signpost the patient to appropriate alternative services.

2.3 Considerations when developing a form-based assessment for HRT

To determine which type of HRT is appropriate for an individual patient, it is recommended that the initial form-based assessment includes question(s) about:

- Age, height and weight
- Results and dates of last blood pressure check and last blood test
- Complete history of relevant medical conditions (e.g. diabetes mellitus, high cholesterol, cancer) and current medication use
- Complete family history of relevant medical conditions (e.g. oestrogen-sensitive cancer)
- Prior hysterectomy
- Date of last period (to determine whether sequential or continuous treatment is needed)
- Current and previous menopause symptoms
- Date of most recent visit to their GP or private doctor to talk about their menopause symptoms
- Diagnosis of early menopause or POI
- Current and previous use of HRT, including any symptoms while on treatment
- Prior mammogram and regular checks for lumps or changes in breast tissue
- Most recent cervical screening
- Current contraceptive use.

Providers may also wish to include a mechanism by which patients can confirm they understand that providing incorrect information may cause harm. For their own safety, all answers must be accurate to the best of the patient's knowledge.

3. Considering the patient journey

Recently, supply shortages in HRT medicines have been a concern [38–40]. If a particular medicine becomes unavailable once HRT has already been started, options for switching to another type or brand of HRT should be discussed with the patient [29,30]. Stopping HRT due to a supply shortage is not advised [40].

There have also been concerns in the media about women being overprescribed or overusing HRT [41]. A joint safety alert published by multiple stakeholders in April 2023 emphasises the importance of aiming to treat menopause symptoms using the lowest effective dose of HRT, in line with NICE, MHRA and other national and international guidance [42].

A woman's health circumstances will change as she gets older and there may be pivotal health events where her HRT and general hormonal health need to be reassessed. Such events include, but are not limited to, heart attack [43], fracture leading to a bone density assessment [44], and breast cancer [45].

4. Recommendations from the DiCE Working Group

4.1 Who should follow these recommendations?

The following recommendations are intended as best practice guidance for developing form-based assessments to allow online providers to safely initiate HRT in peri- and post-menopausal women seeking treatment for menopause-related symptoms (see section 2.3 for more details).

The recommendations in this guidance document are intended to complement current prescribing information for HRT medicines in women. They are not intended to include all considerations for all available types and doses of HRT. Online providers should always refer to the BNF and Summary of Product Characteristics before prescribing any type of HRT in patients seeking treatment. Relevant NICE, SIGN and other national guidelines produced by statutory bodies should also be followed. An updated version of the current NICE menopause guidelines is in development, having recently completed the draft consultation phase [46].

Recommendations for initial consultation and prescribing

A patient may be eligible for HRT:

– If they were assigned female at birth

- HRT is not licensed for use in patients assigned male at birth.
- Although transwomen may experience symptoms similar to those of menopause, they do not experience menopause itself [47].

– If they are aged 45 years or older and have self-reported symptoms consistent with the menopause, and these symptoms are adversely affecting their quality of life

- Prescribers should be aware that the use of HRT medicines in patients over 65 years old is based on limited clinical experience.

– If they are under 45 years of age and have a confirmed diagnosis of early menopause or POI

- Some participants in the DiCE Working Group currently request that patients under 45 years of age provide proof of menopause diagnosis and/or the results of a follicular stimulating hormone test before making a prescribing decision.
- If they are unable to provide this proof, the patient is referred to their GP or private doctor for further consultation.

– If they are under 45 years of age and have had a hysterectomy

- Some participants in the DiCE Working Group currently request that patients under 45 years of age provide proof of hysterectomy (e.g. GP or hospital letter).
- If they are unable to provide this proof, the patient is referred to their GP or private doctor for further consultation.

Use caution when prescribing HRT:

– If the patient has untreated high blood pressure or high cholesterol, or has not had their blood pressure or cholesterol measured within a reasonable time period [29,30,47]

- Advise the patient to consult their GP or private doctor for examination and further advice.

– If the patient has a known or suspected diagnosis of diabetes, kidney disease, gallstones, or any type of liver condition [29,30,48,49]

- Ask the patient to provide further details before making a prescribing decision for HRT.
- This caution may not apply to all types of HRT medicines (e.g. those with minimal systemic effect). Prescribers should always refer to the individual product information for specific guidance.

– If the patient has a known or suspected diagnosis of epilepsy or suffers from migraine [29,30,35]

- Ask the patient to provide further details before making a prescribing decision for HRT.
- If HRT is prescribed, women with migraine should be treated transdermally and not with oral tablets [35].

– If the patient has a known or suspected cardiovascular condition (e.g. angioedema, atrial fibrillation, angina), or has other known risk factors for cardiovascular disease (e.g. obesity, diabetes, lupus, immediate family history of heart attack) [29,30]

- Ask the patient to provide further details before making a prescribing decision for HRT.
- This caution may not apply to all types of HRT medicines (e.g. those with minimal systemic effect). Prescribers should always refer to the individual product information for specific guidance.

– If the patient has a history of stroke, transient ischaemic attack or cerebral haemorrhage [29,30]

- Ask the patient to provide further details before making a prescribing decision for HRT.
- This caution may not apply to all types of HRT medicines (e.g. those with minimal systemic effect). Prescribers should always refer to the individual product information for specific guidance.

– If the patient has an immediate family history of oestrogen-sensitive cancer [50,51]

- Ask the patient to provide further details before making a prescribing decision for HRT.
- This caution may not apply to all types of HRT medicines (e.g. those with minimal systemic effect). Prescribers should always refer to the individual product information for specific guidance.

– If the patient has a known or suspected diagnosis of uterine fibroids or endometriosis, or a history of untreated endometrial hyperplasia [29,30]

- Ask the patient to provide further details before making a prescribing decision for HRT.

– If the patient has current symptoms of a vaginal infection (e.g. thrush or bacterial vaginosis)

- An active vaginal infection may be resolved by local (vaginal) HRT with or without antibiotics [52,53].
- Advise the patient to consult their GP or private doctor for examination and further advice before making a prescribing decision for HRT.

Consider not prescribing HRT:

– If the patient has previously used HRT and experienced unexpected vaginal bleeding and/or discharge while taking HRT [29,30]

- Although vaginal bleeding is a common side effect of HRT within the first 3 months of treatment, bleeding after the first 3 months may indicate the presence of endometrial cancer [22].
- Advise the patient to consult their GP or private doctor for examination and further advice before making a prescribing decision for HRT.

Do not prescribe HRT:

– If the patient has a known or suspected breast cancer or other oestrogen-sensitive cancer such as endometrial or ovarian cancer [29,30]

- HRT may still be permitted in this situation but should only be prescribed by the patient's GP or private doctor, or an HRT specialist, after a full discussion of the risks and benefits.

– If the patient has a known or suspected diagnosis of porphyria [29,30]

- HRT may still be permitted in this situation but should only be prescribed by the patient's GP or private doctor, or an HRT specialist, after a full discussion of the risks and benefits.

– If the patient has unexplained vaginal bleeding or severe vaginal itching or discharge [29,30]

- Inform the patient that they should urgently consult their GP or private doctor for examination and further advice.
- HRT may still be permitted in this situation but should only be prescribed by the patient's GP or private doctor, or an HRT specialist, after a full discussion of the risks and benefits.

– If the patient is being treated for or has a history of deep vein thrombosis (DVT) or pulmonary embolism (PE), or has any condition that increases the risk of DVT/PE [29,30]

- HRT may still be permitted in this situation but should only be prescribed by the patient's GP or private doctor, or an HRT specialist, after a full discussion of the risks and benefits.

– If the patient is pregnant or currently breastfeeding [54,55]

- Women who become pregnant while taking HRT should stop taking HRT and consult their GP or private doctor for further advice.
- HRT may still be permitted in this situation but should only be prescribed by the patient's GP or private doctor, or an HRT specialist, after a full discussion of the risks and benefits.

– If the patient has a known hypersensitivity, or any other contraindications according to the individual product information

4.3. Recommendations for monitoring and review

It can take up to 3 months for the full benefits of initiating HRT to become apparent [29,30].

The consensus among participants in the DiCE Working Group is that monitoring for side effects should take place within 2–4 weeks of starting HRT, and that a review of HRT medicines is recommended at the time of prescription refill (repeat supply).

A full review of HRT use, including a comprehensive risk vs. benefit analysis, is recommended at least once annually for all patients, to ensure that the continuing use of HRT adheres to national guidance (i.e. using the lowest effective dose for the shortest period of time necessary to control symptoms). This review should take place even if the patient's symptoms are stable. For example, patients who start on cyclical HRT during peri-menopause may benefit from switching to continuous combined HRT post-menopause [30].

Providers should ensure that patients are able to contact them to report any treatment-emergent side effects while taking HRT medications.

Recommendations

In addition to the product's patient information leaflet, online prescribers should provide patients with:

- Advice around diet and exercise, and information about resources available to help patients make lasting changes to their lifestyle.
- Advice about stopping treatment if they develop symptoms of cancer, thromboembolism, unexpected vaginal bleeding, severe vaginal itching or discharge, or have any other potentially serious side effect of HRT medications, and how they can seek help.
- Pregnancy and contraceptive advice, where appropriate.
- Advice on how to self-report side effects of treatment to the MHRA using the Yellow Card online reporting tool for patients.

Monitor patients for side effects within 2–4 weeks of starting HRT:

- Patients should be encouraged to report any side effects, in addition to any that they may have reported to the MHRA.

Conduct a full review of patient's treatment plan at time of prescription refill (at least once annually), including a comprehensive risk vs. benefit analysis:

- As part of this review, patients should have the opportunity to update their medical history, access clinical consultation and provide the necessary information to continue their treatment.
- If, at any time, continuing treatment constitutes an off-label use of HRT medicine, the implications of this should be clearly communicated to the patient.
- Prescribers should keep a clear written record of their discussions with the patient, including justification for treatment decisions made.

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