PRIMARY CARE
WOMEN'S HEALTH FORUM

How to manage HRT provision without face to face consultations during COVID-19 healthcare restrictions

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This advice has been produced by clinical expert consensus and is endorsed by the British Menopause Society (BMS). It is not intended to replace the need to apply personalised clinical judgement.

In response to the COVID-19 healthcare restrictions, the use of telephone and virtual consultation was endorsed by the BMS, FSRH and RCOG in March 2020.

The Primary Care Women's Health Forum has produced this guide for primary care practitioners in order to provide support for HRT provision during this time. This guide has been endorsed by the British Menopause Society.

Below are menopause management checklist tools designed for remote consultations in primary care.

TOOL FOR INITIATING HRT BY REMOTE CONSULTATION

CHECKLIST	Y/N	TOP TIPS AND WHERE TO FIND MORE INFORMATION, BASED ON NICE MENOPAUSE: DIAGNOSIS AND MANAGEMENT[i]
BMI < 30kg/m2	y/n	Watch for BMI > 30kg/m2, see risk review.
Blood pressure normal	y/n	HRT OK if hypertension well controlled, if no BP available see tip no. 5 on PCWHF tips on HRT provision during COVID-19 healthcare restrictions.
Progestogen required	y/n	Progestogen required unless hysterectomy or 52mgLNG IUS within 5 years document in notes
Last menstrual period < 12 months	y/n	Document perimenopause or post menopause as appropriate
Regular medications		Check GP notes
Past medical history		Check GP notes
Smoker	y/n	How much?
Alcohol > 14 units/week	y/n	Document number of units
Cervical Cytology up to date	y/n	Check GP notes

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QUESTIONS FOR PATIENT		
Do you feel that your symptoms are related to the menopause?	y/n	See Rock My Menopause for symptoms of menopause https://rockmymenopause.com/portfolio-item/symptoms-of-the-menopause/
Which symptoms are you most concerned about?		Document in notes Signpost to 'Symptom Tracker' on Rock My Menopause https://rockmymenopause.com/portfolio-item/symptoms-tracker/
Are you hoping to be prescribed HRT?	y/n	If Yes – Signpost to PIL 'HRT in a nutshell' https://rockmymenopause.com/portfolio-item/hrt-in-a-nutshell/ If No – Signpost to 'Alternatives to HRT' https://rockmymenopause.com/portfolio-item/what-are-the-alternatives-to-hrt/
Have you found out about benefits and potential long-term risks of using HRT?	y/n	Document the source of information or signpost to https://tinyurl.com/w5msp95
Do you have any vaginal dryness or discomfort?	y/n	If Yes – Offer vaginal oestrogen and signpost https://pcwhf.co.uk/resources/vulval-skin-care/ https://rockmymenopause.com/portfolio-item/vaginal-dryness/
Are you attending recommended screening programmes?	y/n	Reiterate advice regarding cytology, mammography and breast awareness https://tinyurl.com/wq3olxk https://www.nhs.uk/conditions/breast-cancer-screening/
Any concerns about vaginal bleeding?	y/n	Please follow NICE guidance as appropriate HMB https://www.nice.org.uk/guidance/ng88 PMB https://tinyurl.com/trum9ub
Are you sexually active?	y/n	Do you have problems in this area?
Are you at risk of pregnancy?	y/n	If in doubt advise contraception until 55yrs[ii] https://pcwhf.co.uk/resources/pcs-c-19-community-contraception-guide/
Have you recently changed your sexual partner?	y/n	Establish STI risk
RISK REVIEW BY PRIMARY HEALTHCARE PRACTITIONER		**Please see NICE (NG23) https://pathways.nice.org.uk/pathways/menopause**
VTE risk?	y/n	Consider transdermal oestrogen if risk, see NICE (NG23)
Arterial risk?	y/n	Consider transdermal oestrogen if risk, see NICE (NG23)
Breast risk?	y/n	For counselling tip see below, signpost to MHRA PIL https://tinyurl.com/y6nhwrry
Bone risk?	y/n	HRT protects bone density, see below https://rockmymenopause.com/portfolio-item/bone-health-and-the-menopause
Metabolic issues?	y/n	If liver disease, malabsorption, thyroid disorder or diabetic non orals preferred
HRT recommended?	y/n	Oestrogen only, Sequential combined or Continuous combined? If Y, see https://tinyurl.com/vh2j3jj If N, see https://tinyurl.com/y94llcwt
Vaginal HRT indicated?	y/n	
Next HRT review OK for 12 months?	y/n	It is recommended by NICE (NG23) after initiation to review at 3 months and once stabilised annually

TOOL FOR REVIEWING HRT BY REMOTE CONSULTATION

HRT REVIEW CHECKLIST	Y/N	TOP TIPS AND WHERE TO FIND MORE INFORMATION
BMI < 30kg/m2	y/n	Watch for BMI > 30kg/m2, see risk review.
Blood pressure normal	y/n	HRT OK if hypertension well controlled
Progestin required	y/n	Unless hysterectomy or 52mgLNG IUS within 5 years
HRT supply difficulty?	y/n	For HRT converter see PCWHF tips on HRT provision during COVID-19 healthcare restrictions. For current availability follow: https://tinyurl.com/y9j8yqak https://www.mims.co.uk/drug-shortages-live-tracker/article/1581516 For equivalant alternatives see: https://tinyurl.com/vh2j3jj
QUESTIONS FOR PATIENT		
Is the HRT helping symptoms?	y/n	
Any side effects?	y/n	For HRT side effects troubleshooter, see below
Any change to your health since your last HRT check?	y/n	Document in notes
Any change to your other medications since your last HRT check?	y/n	Document in notes
Do you have any vaginal dryness or discomfort?	y/n	If Yes – Offer vaginal oestrogen and see PIL on vulval care https://pcwhf.co.uk/resources/vulval-skin-care/
Are you attending recommended screening programmes?	y/n	Reiterate advice regarding cytology, mammography and breast awareness, see PIL https://tinyurl.com/wq3olxk
Any concerns about vaginal bleeding?	y/n	For tips on bleeding, see PCWHF tips on HRT provision during COVID-19 healthcare restrictions.
Do you need contraception?	y/n	If in doubt, advise contraception until 55yrs[iii] https://pcwhf.co.uk/resources/pcs-c-19-community-contraception-guide/
RISK REVIEW BY PRIMARY HEALTHCARE PRACTITIONER		
Venous Thromboembolism, new risk?	y/n	Consider transdermal oestrogen if risk, see PCWHF tips on HRT provision during COVID-19 healthcare restrictions.
Arterial, new risk?	y/n	Consider transdermal oestrogen if risk, see PCWHF tips on HRT provision during COVID-19 healthcare restrictions.
Breast, new risk?	y/n	For counselling tip, see PCWHF tips on HRT provision during COVID-19 healthcare restrictions.
Bone, new risk?	y/n	HRT protects bone density, see PCWHF tips on HRT provision during COVID-19 healthcare restrictions.
Metabolic, new risk?	y/n	If liver disease, malabsorption, thyroid disorder or diabetic consider transdermals
Might testosterone add benefit?	y/n	See tip 9 in PCWHF tips on HRT provision during COVID-19 healthcare restrictions and https://pcwhf.co.uk/resources/10-top-tips-on-testosterone-use-for-women
Next HRT review OK for 12 months?	y/n	12 months is OK unless you have concerns

HRT PRESCRIBING TOOL

For up to date stock availability follow: MIMS https://www.mims.co.uk/drug-shortages-live-tracker/article/1581516

OESTROGEN ONLY (no uterus or IUS)	SEQUENTIAL COMBINED (uterus – monthly bleed)	CONTINUOUS COMBINED (uterus – no bleed) Lmp > 1 yr ago if > 50yrs Lmp > 2yrs if < 50 yrs
PATCHES		
Available as brands **Twice weekly patch** E2 40/80 E2 25/50/75/100 E2 25/37.5/50/75/100 E2 50/75/100 **Once weekly patch** E2 50 (mcg/24hrs)	**Mix and Match** E2 + MPA 10mg cyclical E2 + MP 200mg cyclical **Available as brands** E2 50mcg + LNG 10mcg cyclical E2 50mcg + NET 170mcg cyclical	**Mix and Match** E2 + MPA 5-10mg conti E2 + MP 100mg conti **Available as brands** E2 50mcg + NET170mcg E2 50mcg + LNG 7mcg
GELS		
Daily E2 Pump-Pack 0.06% E2 gel sachets 0.5/1mg	E2 + MPA 10mg cyclical E2 + MP 200mg cyclical	E2 + MPA 5-10mg conti E2 + MP 100mg conti
ORAL HRT		
CEE 0.3/0.625/1.25mcg	No branded option	CEE 0.3/1.5MPA continuously
E2 0.5mg (use half of 1mg)	No branded option	**Available as brand** E2 0.5+ 2.5mg dydro conti
E2 1mg	**Mix and Match** E2 1mg + MPA 10mg cyclical E2 1mg + MP 200mg cyclical **Available as brands** E2 1mg + cyclical dydro E2 1mg with cyclical NET	**Mix and Match** E2 1mg + MPA 5-10mg conti E2 1mg + MP 100mg conti **Available as brands** E2 1mg + 5mg dydro conti E2 1mg + NET 0.5mg conti E2 1mg + MPA conti
E2 2mg	**Mix and Match** E2 2mg + MPA 10mg cyclical E2 2mg + MP 200mg cyclical **Available as brands** E2 2mg + with cyclical dydro E2 2mg with cyclical NET E2 2mg + MPA long cycle	**Mix and Match** E2 2mg + NET1mg conti E2 2mg + MPA conti **Available as brands** E2 2mg + NET 1mg conti E2 2mg + MPA 5mg conti
Estradiol valerate 1mg/2mg	No branded option	No branded option
No branded option	No branded option	Tibolone 2.5mg

TABLE KEY

CEE – Conjugated equine estrogen

Conti – Continuous regime

Cyclical progestogen regime – for last 14-28 days of each cycle

Dydro – Dydrogesterone (mildly anti androgenic progesterone derived progestogen)

E2 – Estradiol

LNG – Levenorgestrel (androgenic)

MP – Micronised progesterone (Body identical)

MPA – Medroxyprogesterone acetate (progestogenic with high endometrial affinity)

NET – Norethisterone (androgenic progestogen)

PCWHF tips on HRT provision during COVID-19 healthcare restrictions

It is OK to prescribe up to 12 months of HRT providing you are happy with the HRT check

This is based on NICE guideline [NG23] Published date: November 2015

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. HRT CONVERTER: HOW TO CONVERT OESTRADIOL GELS & PATCHES

TIP – 1.5mg estradiol gel = 50mcg patch = 2mg oral oestradiol are reasonably bioequivalent

2. HRT AVAILABILITY AND EQUIVALENTS

- If you can't get hold of an oestrogen only patch, then consider swapping to gel
- If swapping patches, brands will differ because of glue, some patches stay on better than others
- Beware weekly and twice weekly regimes when prescribing patches
- The BMS had produced a really helpful document entitled *HRT preparations and equivalants*, which details brand names https://tinyurl.com/vh2j3jj

Twice weekly Elleste Solo (40, 80mcg/24hrs), Evorel (25, 50, 75, 100mcg/24hrs), Estradot (25/37.5/50/75/100mcg/24hrs)

Weekly patch – Progynova TS (50, 75, 100mcg/24 hrs)

- Combination patches such as Evorel Conti and Femseven Conti give a fixed dose making adjustment more difficult
- If you cannot get hold of a combined patch, swap to oestrogen only with an oral progestogen
- If you can't get hold of oral combined HRT, swap to transdermal oestrogen only gel, patch or tablet with an oral progestin cyclically or continuously as appropriate
- Suggested oral progestogens – Sequential/Cyclical: Micronised progesterone 200mg or Medroxyprogesterone acetate 10-20mg forlast 14 days of 28 days cycle
- Continuous: Micronised progesterone 100mg at bedtime or Medroxyprogesterone acetate 5-10mg daily
- Norethisterone is unlicensed for the progestogenic opposition of Oestrogen HRT. However, recommendations from the BMS suggest: Norethisterone could be considered as well. Cyclical: 5 mg a day for 12 days a month. Continuous: 1mg NET are no longer available so consider NET 1.05mg (as 3 x Noriday if in stock). If ongoing bleeding issues can increase to 5 mg a day in a continuous combined regimen.

- During the shortage of HRT, prescribers must consider all options available to women, and oral HRT's containing oestradiol with dydrogesterone are viable alternatives for women without additional risk factors for VTE, and some may even consider this to be a more convenient option.

  Observational studies have demonstrated that the combination of oestradiol and dydrogesterone (for example Femoston® and Femoston® conti) may be associated with a lower breast cancer and VTE risk compared to other preparations, and therefore should be considered as a suitable alternative[a].

To know more about current availability:

MIMS https://tinyurl.com/ydgo99be
British Menopause Society https://thebms.org.uk/news/

3. HRT SIDE EFFECTS AND TROUBLE SHOOTING

The main side effects of taking oestrogen include bloating, breast tenderness or swelling, feeling sick, leg cramps, headaches, indigestion. Consider changing to transdermal or if on transdermal adjusting dose.

The main side effects of taking progestin include breast tenderness, swelling in other parts of the body, headaches or migraines, mood swings, depression, acne, GI side effects. If on oral, consider swapping the progestin to dydrogesterone, or if on combined patch consider swapping to estradiol only with oral progesterone e.g. micronised progesterone or Medroxyprogesterone acetate

4. UNSCHEDULED VAGINAL BLEEDING AND HRT

The RCOG, BSGE and BGCS recommend remote consultation and minimising gynaecological procedures. In practice, this means that as primary care practitioners, access to hysteroscopy will be limited.

TIP – As usual, unscheduled bleeding of any duration consider pregnancy, STI and cervical cytology as appropriate. Please also see the PCHWF's resource How to manage women presenting with abnormal vaginal bleeding in primary care without face to face contact. *https://tinyurl.com/ydhuhw7c*

Follow on from recent advice from the British Menopause Society[v] https://thebms.org.uk

TIP – Unscheduled bleeding < 6 months (common in first 3-4 months of HRT)

IUS and HRT

- Keep IUS in situ and add in progestin MP, MPA or NET or swap to cyclical progestogen regime (see the HRT prescribing resource.)

Cyclical HRT

- Increase progestin dose (MPA 20mg or MP 300mg for 12-14 days for 28-day cycle or)
- Or duration (e.g. MPA 20mg for 21 days of 28-day cycle)
- Or type (e.g. Medroxyprogesterone acetate has good endometrial affinity and may provide the best bleed control)

Continuous combined HRT

- Increase progestin dose (e.g 100mg MP to 200mg daily, 5mg MPA to 10mg)
- Swap progestin (to MPA or NET)

TIP – If unscheduled bleeding > 6 months consider further investigation (e.g. pelvic ultrasound and endometrial biopsy) or write for advice and guidance from local hysteroscopy service

a. Stevenson J. Gray S. Hormone replacement therapy (HRT) shortage: switching to Femoston® (estradiol/dydrogesterone) from an alternative combination oral or transdermal HRT. Guidelines Nov 2019. Available from: https://www.guidelines.co.uk/supplements/hormone-replacement-therapy-hrt-shortage-switching-to-femoston-estradiol/dydrogesterone-from-an-alternative-combination-oral-or-transdermal-hrt/455066.article Accessed 22/04/20

5. NICE (NG23) RECOMMENDS ANALYSIS OF INDIVIDUALISED LONG-TERM BENEFITS AND RISKS OF HORMONE REPLACEMENT THERAPY

Venous Thromboembolism – If BMI > 30kg/m2 consider swapping to oestradiol patch/gel, ensure not on high dose norethisterone, this is because:

NICE (NG23) states that:

- The risk of VTE associated with the use of HRT is greater for oral than transdermal preparations
- The risk associated with transdermal HRT given at a standard therapeutic dose is no greater than baseline population risk

Cardiovascular – If it is less than 10 years since LMP, then benefits are likely to outweigh risks. Stopping and restarting HRT is less safe than staying on it. If in doubt swap to patch or gel.

If no recent BP reading available, if personal arterial or venous risk factors including hypertension use non orals, if no problems in the past and no risk factors oral may be reasonable (HRT does not raise BP).

NICE (NG23) states that HRT:

- does not increase cardiovascular risk when started in women aged under 60 years
- does not affect the risk of dying from cardiovascular disease
- HRT with progestogen is associated with little or no increase in the risk of coronary heart disease
- Taking oral (but not transdermal oestrogen) is associated with a small increase in the risk of stroke

Breast Cancer – Putting the risk into context can help. Alcohol and obesity have been shown to be associated with a higher risk compared to that with HRT.

NICE states that:

- Any increase in the risk of breast cancer is related to treatment duration and reduces after stopping HRT
- 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

However, in August 2019, the MHRA issued further information on the known increased risk of breast cancer with HRT and its persistence after stopping. This is the link to the PIL:

Medicines and Healthcare products Regulatory Agency. Hormone replacement therapy and risk of breast cancer. August 2019. Available from: https://assets.publishing.service.gov.uk/media/5d68d0e340f0b607c6dcb697/HRT-patient-sheet-3008.pdf

There are a number of documents on the BMS website on interpretation of the Lancet paper.
https://tinyurl.com/yb4w4kca
https://thebms.org.uk/

Osteoporosis – Benefits of HRT for bones is particularly important for women at higher risk of osteoporosis (e.g. premature ovarian insufficiency)

NICE states that:

- the 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

TIP – check out www.sheffield.ac.uk/FRAX/ for a useful fracture risk assessment tool

6. METABOLIC CONSIDERATIONS

TIP – If patients are on Levothyroxine, absorption may be affected by HRT. Clinical experience suggests that they may get on better with transdermal than oral oestrogen.
Type 2 Diabetes - no need to stop HRT in diabetic patients, consider swapping to patch or gels if cardiovascular risk.

7. IUS RULES

Mirena for HRT

- If Mirena is > 5 yrs add oral progestogen such as MPA 5-10mg or Utrogestan 100mg daily

If Mirena is inserted for the purpose of HRT, FSRH recommendation is that it can stay in for 5 years (licensed for 4 years) with oestrogen therapy but if is more than 5 years then her HRT should be changed from oestrogen only to a combined HRT preparation.

Mirena for Contraception

Mirena is licensed for 5 years use for contraception. FSRH advice is that if the Mirena is between 5 and 7 years since it was changed then contraceptive cover continues. So, no need to change now. An IUS placed over 45 years previously will still act as contraception for a perimenopausal woman until age 55years.[vii]

8. PLEASE REMEMBER VAGINAL HEALTH

Vaginal oestrogen has minimal systemic absorption and is widely considered to be a suitable treatment for Genito Urinary Syndrome of the Menopause.

9. USE OF TESTOSTERONE

Starting testosterone now in primary care is not ideal, as it requires laboratory monitoring which is not available. Patients who are stable on testosterone should continue the established dose.

- Starting testosterone requires laboratory testing which is not currently available
- Write for advice and guidance to gynae/menopause specialist if not confident starting
- Testosterone can be essential for maintaining quality of life particularly those with POI and/or surgical menopause. If there are signs of androgen deficiency in a woman who is on adequate oestrogen replacement, then testosterone replacement should may be considered if the clinician feels confident to do so.
- For clear guidance https://tinyurl.com/shu6fr3

10. FOR FURTHER PRACTICAL CLINICAL ADVICE PLEASE FOLLOW:

- https://thebms.org.uk
- www.womens-health-concern.org
- www.menopausematters.co.uk
- www.managemymenopause.co.uk

i. NICE. Menopause: diagnosis and management. (2015). NICE guideline [NG23] Published date: November 2015 Last updated: December 2019 Available at: https://www.nice.org.uk/guidance/ng23

ii. FSRH Guidance for contraception for women over 40. (2019). Available at: https://www.fsrh.org/documents/fsrh-guidance-contraception-for-women-aged-over-40-years-2017/fsrh-guideline-contraception-aged-over-40-sep-2019.pdf (accessed 28/03/2020)

iii. FSRH Guidance for contraception for women over 40. (2019). Available at: https://www.fsrh.org/documents/fsrh-guidance-contraception-for-women-aged-over-40-years-2017/fsrh-guideline-contraception-aged-over-40-sep-2019.pdf (accessed 28/03/2020)

iv. RCOG, BSGE and BGCS guidance for the management of abnormal uterine bleeding in the evolving Coronavirus (COVID-19) pandemic. (March 2020) Available at: https://mk0britishsociep8d9m.kinstacdn.com/wp-content/uploads/2020/03/Joint-RCOG-BSGE-BGCS-guidance-for-management-of-abnormal-uterine-bleeding-AUB-in-the-evolving-Coronavirus-COVID-19-pandemic.pdf (accessed 31/320)

v. BMS (31st March 2020) BMS statement on the RCOG/BSGE/BGCS document on the management of irregular menstrual bleeding/ postmenopausal bleeding. https://thebms.org.uk (accessed 1/4/20)

vi. NICE. Menopause: diagnosis and management. (2015). NICE guideline [NG23] Published date: November 2015 Last updated: December 2019 Available at: https://www.nice.org.uk/guidance/ng23 (accessed 28/03/2020)

vii. PCWHF. How to manage contraceptive provision without face to face consultations. Available at: https://pcwhf.co.uk/resources/how-to-manage-contraceptive-provision-without-face-to-face-consultations/ Accessed 28/03/2020