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An Audit on High dose Oestrogen HRT prescribing in General Practice.

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I. BACKGROUND:

Menopause impacts a significant number of women, with symptoms thatconsiderably affect their quality of life.

There has been a 35% increase in Hormone Replacement Therapy (HRT) prescribing from2021 to 2022[1].More women are now being prescribed higher doses of oestrogen.Unfortunately,as the use of micronized progesterone increases, it is becoming evident that it may not alwaysbe effective at keeping the endometrial lining thin, resulting in unscheduled bleeding.

Unscheduled bleeding (USB)occurs in approximately 40% of women taking HRT[2]. This is leading to additional strain on both primary care and secondary care, leading to an increasein suspected cancer referrals, and causing unnecessary worry and investigation for patients.

In April 2024, the British Menopause Society (BMS) issued a new joint guideline, recommending changes to the dose of progesterone for women on oestrogen for HRT[3], in response to this significant increase. The progesterone dose changes only applied to women on high dose topical oestrogen regimens: oestrogel at 4 pumps daily, patch at 100mcg/day, and spray 6 sprays a day.The BMS advised that theprogesterone dose should be increased in proportion to the oestrogen dose in people who have a uterus, to minimise the risk ofunscheduled bleeding and endometrial cancer.

Route of administration	Dose per day
Oestrogel	4 pumps
Patch	100mcg
Oral Oestradiol	4mg*

Microionised Progestogen (e.g. Utrogestan)	
Every day	2 weeks on 2 weeks off
200mg	300mg

BMS Management of Unscheduled Bleeding on HRT

Aim:

To assess whether patients on HRT are receiving the appropriate dose of progesterone in line with BMS recommendations.

Standards and Criteria:

This is based on NICE NG23/BMS.[4]
All women on high-dose topical oestrogen should receive progesterone cover consistent with BMS 2024 dosing recommendations.
Target: 100%

II. METHODS:

Setting: Audit of HRT Prescribing atMedical Centre against standards from BMS Guidance.
Population: All women prescribed HRT during the audit period of July 2024 to July 2025.
Sample: A search was carried out by the Practice Manager using EMIS electronic health records. Data accuracy was ensured by individually checking records and prescriptions and confirming details through patient discussions where appropriate.
Data Points: Type/route HRT, dose, progesterone cover documentation on prescription

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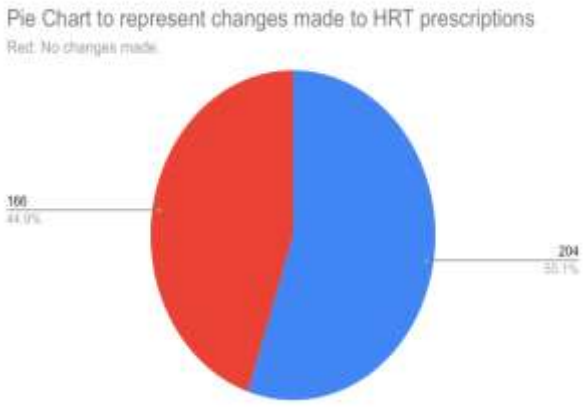
Exclusions: Patients on oral HRT, patients on oestrogen for Gender Reassignment
Re-audit was carried out after 3 months for the prescribing against the same standards.

III. RESULTS:

415 women were identified to be on HRT.
9 patients were excluded: GID/ Hypogonadism / Oral HRT
36women hadstopped taking HRT
61women were on highstrength topical oestrogen doses
13women had aMirena/ hysterectomy
48 women were on oral progesterone which were not adequate strength as per the new BMS recommendations

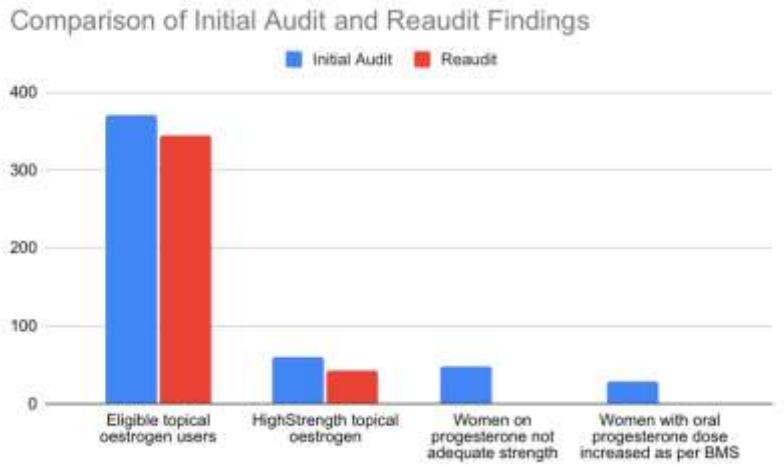
Following discussions by GP/ Clinical Pharmacist:
29women had oral progesteronedosesincreased
19 women who were initially using high strength topical oestrogen, had their doses dropped down to moderate strength

In total, 204 prescriptions were amended to reflect the accurate dose of oestrogen: number of pumps or sprays of oestrogen, and the type of progesterone cover on the prescription:dose of oral progesterone, orMirena with expiry date.



Re- Audit after 3 months:

354 women identified to be on HRT.
9 patients were excluded: GID/ Hypogonadism/ Oral HRT
42women wereusing high strength topical oestrogen doses:
13 women had a Mirena/ hysterectomy
29 women were taking corresponding high dose oral progesterone
All prescriptions confirm route/ dose/ progesterone cover.



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IV. DISCUSSION:

370 women were identified to be on topical oestrogen for HRT.Among them, 61 women (15%) were using high strength topical oestrogen: 100mcg patch, 4 pumps oestrogen, 6 sprays Lenzetto.

48 women required furtherdiscussions about theupdated guidelines, appropriate progesterone dosing, and the related risks.

All women prescribed oral progesterone were given Utrogestan (micronised progesterone) for the progesterone part of their HRT.

According to the new BMS guidelines:

There is not sufficient data to provide guidance on the endometrial cancer risk when micronised progesterone, at a dose used for low or standard dose oestrogen, is used in combination with moderate or high dose oestrogen. Until evidence relating to safety with moderate and high dose oestrogen is available, a pragmatic approach needs to be considered, as the risk to the breast tissue from increasing the progesterone dose is also unknown.[4]

Recent research has shown that oestrogens combined with oral micronised progesterone do not increase breast cancer for up to 5 years of treatment duration. However, there is limited evidence that oestrogens combined with oral micronised progesterone for more than 5 years are associated with an increased breast cancer risk.[5]

Options discussed included:

1. Reducing the oestrogen dose from high strength to moderate strength.
2. Increasing progesterone dose in accordance with BMS recommendations, whilst being provided with counselling on the unknown increased risk of breast cancer.
3. Considering a switch to Mirena coil.

Of the 48 women on high-strength topical oestrogen, 19 (40%) chose to reduce their dose to moderate strength. No changes to the oral progesterone dose were required.

29 women (60%) continued with high-strength oestrogen, and their oral micronised progesterone dosage was increased as per BMS guidance.

Decisions regarding oestrogen dose reductions, or increases in progesterone involved clinical discussions by a GP, or Clinical Pharmacist. These discussions may inevitably vary by clinician, potentially introducing bias and affecting patient decisions.

Of the 370 women, 204 prescriptions (55%) required amendments to ensure safe and accurate prescribing.

The re-audit confirmed no further progesterone dose changes were required, indicating that previous adjustments were effective.

It is important to highlight this audit did not include those women receiving off-license high doses of oestrogen, exceeding the doses recommended by the British Menopause Society. These patients are having their HRT prescribed by private menopause clinics. As a practice, only high strength doses of oestrogen as recommended by BMS guidance are prescribed by the GPs.

V. CONCLUSION:

This audit identified the need for greater consistency in the prescribing and monitoring for patients using high dose topical oestrogen HRT.

Patients who hadpreviously beenprescribed higher strength oestrogen were reviewed, and thepotential risks and side effectswere discussed. Changes were made to ensure safety when necessary.This includedswitching to aMirena coil for progesterone cover, increasing the oral progesterone dose, or reducing oestrogento moderate dose.

The audit reinforces the importance of reviewing all women on HRT at least once a year,to confirm that treatment remainsappropriate, and that the lowest effective dose is being used to managesymptoms and minimise risk.

Additionalactions to considerinclude HRT review templates to ensure safe prescribing, as well as educational sessions for GPs and nurses.

REFERENCES:

[1]. The Pharmaceutical Journal/ NHSBSA Statistical report
[2]. BMS Joint Guideline 2024
[3]. BMS in partnership with the British society of Gynaecological Endoscopy, British Gynaecological Cancer Society, Faculty of Sexual and Reproductive Healthcare, Getting It Right First Time GIRFT, and the Royal College of Obstetrics and Gynaecologists.
[4]. NICE NG23/BMS
[5]. Climacteric 2018 Apr;21(2):111-122 The impact of micronised progesterone on breast cancer risk: A systematic review. P Stute, L Wildt, J Neulen