



KARNATAKA STATE OBSTETRICS AND GYNECOLOGY ASSOCIATION ETHICS AND MEDICOLEGAL COMMITTEE

MEDICOLEGAL BULLETIN

Week 28: Menopausal Hormone Therapy – Cancer, Thrombosis, Informed Consent, and Medicolegal Responsibility

1. REAL LIFE CASE SCENARIO

A 53-year-old postmenopausal woman with troublesome hot flushes, night sweats, and sleep disturbance was started on systemic menopausal hormone therapy (MHT). She had an intact uterus. Several months later, she developed postmenopausal bleeding and underwent further evaluation. During review, the patient stated that she had not understood the need for individualized risk assessment, the importance of reporting new vaginal bleeding, or the potential risks and benefits of systemic hormone therapy. The medicolegal issue was not simply: "Did MHT cause the subsequent problem?" The more important questions were: "Was MHT appropriately indicated, were contraindications assessed, was the correct regimen selected, were material risks and alternatives discussed, and was follow-up properly documented?" MHT is effective treatment when appropriately prescribed. Medicolegal vulnerability arises when individualized assessment, counseling, regimen selection, or follow-up is inadequate.

2. MEDICOLEGAL RISKS IN SUCH CASES

Menopause treatment is increasingly individualized, and risk varies according to age, time since menopause, formulation, dose, route, duration, and whether a progestogen is required. Common medicolegal allegations include:

- MHT prescribed without adequate medical history or risk assessment
- Failure to investigate unexplained vaginal bleeding before starting therapy
- Estrogen prescribed without appropriate endometrial protection in a woman with an intact uterus
- Failure to consider breast cancer, thromboembolic, cardiovascular, or liver-related risks
- Failure to discuss reasonable nonhormonal alternatives
- Inadequate counseling regarding benefits and potential harms
- Failure to reassess therapy periodically
- Ignoring new postmenopausal bleeding while the patient is receiving MHT
- Treating MHT as a "one prescription forever" therapy

The presence of a complication does not automatically prove negligence. The quality of the decision-making process matters.

3. WHAT GOOD CLINICAL AND MEDICOLEGAL PRACTICE EXPECTS

Before systemic MHT is prescribed, the clinician should individualize the decision.

Important considerations include:

- Age and time since menopause.
- Whether the uterus is present.
- Unexplained vaginal bleeding.
- Previous venous thromboembolism or important thrombotic risk
- Cardiovascular and cerebrovascular disease.
- Current medications and other relevant comorbidities.
- Patient preferences and available alternatives
- Severity and impact of menopausal symptoms
- Personal and relevant family history
- Breast and gynecological cancer history
- Liver disease

Current menopause guidance emphasizes individualized benefit-risk assessment and periodic reevaluation rather than a single universal regimen for every woman.

For many healthy symptomatic women younger than 60 years or within approximately 10 years of menopause onset, the benefit-risk profile of MHT may be favorable when contraindications are absent. This should never be converted into a blanket rule; the individual patient still requires assessment.

4. INFORMED CONSENT – WHAT SHOULD BE DISCUSSED

Counseling should be proportionate to the proposed therapy and the patient's individual risk.

Discuss:

- Expected symptom benefit
- Whether systemic or local therapy is being considered
- Need for progestogen/endometrial protection when clinically required
- Potential thromboembolic and vascular risks
- Breast-related considerations, which vary with regimen and duration
- Possibility of bleeding or spotting and when it requires evaluation
- Relevant alternatives, including nonhormonal options
- Need for follow-up and periodic reassessment

Do not frighten the patient with an indiscriminate list of every theoretical complication.

The goal is informed shared decision-making—not defensive medicine.



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5. DOCUMENTATION – THE DOCTOR'S STRONGEST DEFENSE

The clinical record should clearly document:

- Menopausal symptoms and their severity.
- Whether the uterus is present.
- Important contraindications/risk factors assessed.
- Treatment options discussed.
- Major benefits and material risks explained.
- Warning symptoms explained.
- Menstrual/menopausal history
- Relevant personal and family history
- Examination and investigations where clinically indicated
- Chosen MHT formulation, dose, route, and regimen
- Alternatives discussed
- Follow-up plan

A useful entry may read:

“Individualized benefits and risks of MHT discussed, including thromboembolic, breast/endometrial and bleeding considerations relevant to this patient. Alternatives discussed. Patient wishes to proceed. Review and warning symptoms explained.”

The note should reflect the actual counseling provided, not a retrospective template added after a complication.

6. PRACTICAL SAFE PRACTICE – WHAT TO DO

- Use MHT for a clear clinical indication.
- Individualize treatment rather than prescribing the same regimen to every patient.
- Use the appropriate estrogen/progestogen strategy according to uterine status and clinical context.
- Consider route of administration when thrombotic risk is relevant.
- Investigate unexplained postmenopausal bleeding appropriately.
- Explain that new or persistent bleeding requires reassessment.
- Reevaluate symptoms, ongoing indication, and risk profile periodically.
- Keep routine age-appropriate preventive care and screening up to date.
- Document why MHT was chosen and why the selected regimen was appropriate.

Good menopause practice is not “give hormones” or “avoid hormones.”

It is individualized risk-benefit medicine.

7. COMMON MISTAKES TO AVOID

- Prescribing MHT without checking whether the uterus is present
- Giving systemic estrogen without appropriate endometrial protection when required
- Starting therapy despite unexplained vaginal bleeding without evaluation
- Ignoring previous thromboembolism or major contraindications
- Promising that MHT is completely risk-free
- Telling every woman that MHT inevitably causes cancer
- Failure to discuss alternatives
- Failure to review therapy for years
- Automatically attributing postmenopausal bleeding to MHT without appropriate evaluation
- Poor documentation of counseling

Both overtreatment and inappropriate avoidance of effective therapy can result from poor understanding of MHT.

8. CLINICAL-LEGAL PEARL

MHT should neither be prescribed casually nor feared indiscriminately.

The safest medicolegal position is:

Appropriate patient → Appropriate indication → Appropriate regimen → Shared decision → Periodic reassessment → Clear documentation.

A complication does not automatically establish negligence.

What becomes difficult to defend is a treatment decision for which no individualized reasoning can be demonstrated.



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9.EVIDENCE / MEDICOLEGAL INSIGHT

Major menopause guidance emphasizes that hormone therapy remains the most effective treatment for vasomotor symptoms and also prevents bone loss and fracture. At the same time, risks differ according to the woman and the treatment used.

Systemic therapy is not appropriate for every patient. Important contraindications or high-risk situations require careful consideration, and oral systemic therapy may carry greater venous thromboembolic risk than transdermal approaches in appropriate patients.

Therefore, medicolegal review should not reduce MHT to the simplistic question:

“Was hormone therapy given?”

The more meaningful questions are:

- Was there a reasonable indication?
- Was the woman's individual risk assessed?
- Was the regimen appropriate?
- Were relevant benefits, risks, and alternatives discussed?
- Was follow-up appropriate?
- Were new warning symptoms acted upon?

Evidence basis: International Menopause Society White Paper on Menopause and MHT (2024) and The Menopause Society Hormone Therapy Position Statement (2022).

10.TAKE-HOME MESSAGE

Menopausal hormone therapy is an evidence-based treatment—not a routine prescription and not a treatment that should automatically be denied because of fear.

Medicolegal protection comes from good clinical reasoning:

Assess → Individualize → Counsel → Prescribe appropriately → Review → Document.

The goal is not to make MHT risk-free.

The goal is to ensure that the right patient receives the right treatment after an informed, individualized decision.

Next Week's Topic: Venous Thromboembolism After Gynecological Surgery – Risk Assessment, Prophylaxis, and Medicolegal Liability



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