GUEST EDITORIAL

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Why evidence-based guidelines on hormones aren't all alike

Medical evidence accumulates at a pace too fast for the individual mortal to absorb. Inevitably, trustworthy guidelines became essential to day-to-day decision-making, particularly regarding the use of estrogen and progestogen in peri- and postmenopausal women.

Frequent updates help interpret proliferating data

A Hormone Therapy Panel of experts in many fields was convened in each of the last 3 years by the North American Menopause Society (NAMS), to review new studies and determine whether recommendations need to be changed, in light of new issues and new evidence. These Position Statements have become the internationally recognized standard of care.

October 6, 2004, a new Position Statement was announced at the annual NAMS meeting in Washington, DC.

In theory, developing a Position Statement according to the principles of evidence-based medicine would seem simple. Identical databases and published evidence should lead to identical consensus statements and clinical guidelines, should they not? Why then do different organizations, after scrutinizing identical evidence, come out with different interpretations and recommendations?

For example, one of the most enduring debates is to what extent evidence based on a select population can be extrapolated to another select population or to the general population. Argument about the populations studied in the Women's Health Initiative and the Nurses Health trials rages vociferously. Neither study is able to consider all the combinations and variations we encounter in practice.

We will always lack a complete database. It is impossible to undertake and complete evidence-based clinical research that incorporates all populations, subpopulations, conflicting and confounding factors, comorbidities, risk factors, and medication permutations.

Practical experience, judgment called into play

What's more, guideline development would be flawed were it to rely entirely on the existing base of evidence at any one time. Development of guidelines must accommodate the clinical and scientific judgment of both the developer and the clinicians who will put the recommendations into practice. The judgment element explains the differing guidelines, in considerable part.

We considered all of these issues as we wrote the new NAMS Position Statement on peri- and postmenopausal estrogen and progestogen usage. Like previous reports, the latest one identifies issues that cannot be resolved now because of insufficient data.

We invite you to scrutinize our latest

New Position Statement

- **No stipulation on starting or stopping hormone therapy**
- **Safety issues of "bioidenticals" same as for estrogen**

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Position Statement. But translating these positions into practice still necessitates taking into account the complete health profile of the individual woman as well as her personal preferences and beliefs. This Position Statement is intended to enhance the quality of patient care and modulate clinical practice. NAMS believes the positions we have taken are fair and credible, and we hope that both you and your patients will find them practical and acceptable.

Ultimately, we have to do the best we can with what we know at the moment.

Recommendations

Consensus points in the new document include some retained from 2003 (*Menopause.* 2003;10:497–506).

Unresolved issues

The Expert Panel found that data were insufficient to answer these questions:

- *Should women who are doing well on long-term hormone therapy (HT) discontinue?*
- *Is there a best way to discontinue HT?*
- *Does a continuous-combined EPT regimen have an effect different from continuous estrogen with sequential progestogen?*
- *Is HT associated with early risk of coronary heart disease?*

on hormone therapy in peri- and postmenopause

New recommendations

Duration

- ET/EPT can be used for a time consistent with treatment goals and provided the patient is monitored regularly; there was no stipulation on when to reduce or stop therapy.

"Bioidenticals" have same safety issues as traditional hormone therapy

- So-called "bioidentical hormones" should be considered to have the same safety issues as traditional postmenopausal hormone therapy until clinical trials can specify their safety and effectiveness. (The statement refers to custom-made alternatives to FDA-approved estrogen and progestogen formulations.)

Breast cancer risk

- The risk of breast cancer probably increases with EPT use but not with ET use.

Coronary heart disease prevention

- The role of both ET and EPT in primary prevention of coronary heart disease remains unclear, especially in younger women starting therapy early and continuing for a number of years; however, until that evidence is forthcoming, ET or EPT should not be used for primary or secondary prevention of coronary heart disease.

Renewed recommendations

Hormones for hot flashes

- Strong endorsement to use ET/EPT for menopause-related symptoms such as hot flashes.

Hormone dosage

- ET or EPT should be limited to the lowest effective dose.

The complete report is in the NAMS official journal, *Menopause* (2004;11:589–600) and can be accessed at www.menopause.org

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—Mary Ellen Pollina, Circulation Director, 10/1/04