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
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.

Conclusions


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?

Recommendations

High Viscosity DERMABOND®

- DERMABOND and high viscosity DERMABOND adhesive should not be used on wounds in vermilion surfaces. DERMABOND and high viscosity DERMABOND adhesive are intended for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, punctures from minimally invasive surgery, and simple, thoroughly debrided, trauma-induced lacerations. DERMABOND and high viscosity DERMABOND adhesive may be used in conjunction with, but not in lieu of, deep dermal stitches.

- DERMABOND and high viscosity DERMABOND adhesive should not be used below the skin because the polymerized material is not absorbed by moist or dry wounds. When closing facial wounds near the eye with DERMABOND and high viscosity DERMABOND adhesive, position the patient so that any run-off of adhesive is prevented from entering the eye.

- DERMABOND and high viscosity DERMABOND adhesive should not be used in high skin tension areas or across areas of increased skin tension, such as knuckles, elbows, or knees, unless the joint will be immobilized during the skin healing period.

- DERMABOND and high viscosity DERMABOND adhesive should be used immediately after closing the tissue gap as the adhesive will not flow freely from the applicator tip after a few minutes. It is unadvisable bonding of intact skin across, or at the skin junction, where the edges of the skin are well apposed. Other agents such as suture, saline, Betadine® Antisepsis, HIBiclens® (chlorhexidine gluconate), or ointment are not expected to immediately leach the bond.

- Safety and effectiveness of DERMABOND and high viscosity DERMABOND adhesive on wounds in patients with peripheral vascular disease, diabetes, insulin-dependent diabetic mellitus, broad cutting disorders, personal or family history of cholesterolemia or hypertension, or burst or limited lacerations, have not been studied.

- Safety and effectiveness of DERMABOND and high viscosity DERMABOND adhesive on the following wounds have not been studied: animal or human bite wounds, puncture or stab wounds.

- Safety and effectiveness of wounds that have been treated with DERMABOND and high viscosity DERMABOND adhesive and then exposed for prolonged periods to direct sunlight or tanning lamps have not been studied.

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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 progesterone 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