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A pioneer in menopause research, Dr. Utian founded the world's first menopause clinic in Cape Town, South Africa, in 1966 and established the Cleveland Menopause Clinic in 1983.

Recipient of many research grants and awards, he is the author of more than 150 scientific publications and five books. He is the Honorary Past-President of the International Menopause Society and Honorary Founding President and Executive Director of The North American Menopause Society. He is also Chairman of the Council of Affiliated Menopause Societies (CAMS) of the International Menopause Society.

Clinical Practice Six Months After the WHI EPT Arm Termination

There is probably one fact all parties impacted by WHI can agree on: Life has been very hectic and confusing since the termination of the EPT arm of the WHI study.

Reams have been written, numerous meetings convened, and multiple medical and medical-related organizations' "consensus statements" released. The NAMS office has at times felt itself to be in the epicenter of a storm. Opinions from all points of view have come in from women, healthcare providers, the pharmaceutical industry, and post-WHI entrepreneurs. NAMS has responded, most notably with its Advisory Panel on Postmenopausal Hormone Therapy statement, which is presented in full in this issue of *Menopause Management*. We are also in the process of revising all of our educational products.

The key issue is how we as healthcare providers should provide "menopause management" now that the dust has begun to settle. Like always, the optimal approach necessitates going "back to basics."

NAMS has always taken the position that menopause is a normal physiologic phase in the female life cycle. The hormonal changes through the menopause transition may result in symptoms, specifically vasomotor and vulvovaginal, and increased risk over time for certain pathologic processes such as osteoporosis. Coincidentally, age, environment, and gene-related problems also begin to escalate beyond the usual age of menopause. The menopause transition, therefore, is the ideal time for a health screen for risk factors for both hormone-related and coincidental diseases, as well as for early evidence of actual presence of pathology. To this end, NAMS will soon be releasing a self-completed, initial-visit menopause-health form to assist in this screening process.

Therapy is broad based, with "good living practices" (healthy diet, exercise, smoking cessation, seat belts, safer sex, moderation in alcohol, drug avoidance, etc.) being the anchor. Under this scenario, some women may benefit from pharmacotherapy, with the latter being prescribed either for prevention or treatment indications. In the broad range of pharmacotherapies available, hormones then are only one option and must be considered if there is a specific indication and if the decision to use them is based on an adequate risk-to-benefit assessment.

It cannot be overemphasized that WHI is a prevention project, and that hormones can be prescribed for preventive or clinical indications, or both. But both the consumer and the provider must clearly understand why hormones are being considered and prescribed.

What does this mean in practical terms? The NAMS Advisory Panel provides some guidance in this respect. The dilemma for the healthcare provider, however, is highlighted by the areas where the NAMS Panel could not reach consensus. Women are demanding specific answers to questions for which we can only provide superficial answers. Largely, truth is opinion; for what mine is worth, the following is my personal take from the literature to the NAMS Panel's unanswered questions:

- *How long should hormone therapy be continued for symptom relief?* The problem, irrespective of how long therapy is prescribed, is that symptoms often recur. What then?

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your
input.

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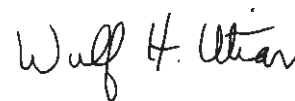
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Return to hormones, alternates with less efficacy, or tough it out? I generally recommend up to 2 to 3 years of hormone therapy, and then an attempt at cessation.

- *Do reasons exist for extended hormone therapy?* Possibly. I certainly have patients with a risk-benefit profile such that therapy can be justified, or who are so impacted by “quality of life” benefits that they will not discontinue. Under these circumstances, it remains our responsibility to explain the risk data as they currently stand. I repeat the conversation at every visit.
- *Does premature menopause/ovarian failure justify long-term hormone therapy?* In my opinion it does, at least until the expected median age of menopause at around 50.
- *Is there a best way to discontinue therapy?* Certainly not that anyone has published to date. Tapering would seem to make sense, but how? We all have our own clinical approach, but it is unlikely there will ever be a “one size fits all.”
- *Do the CEE/MPA data implicate other estrogen/progestogen combinations, dosages, or routes of administration?* We can theorize, but without adequate trials there is no answer. The million-dollar question is whether the FDA will change guidance for product development and the pharmaceutical industry will step to the plate to meet the challenge.
- *Are alternate bone-sparing products safe and effective for extended use in younger women?* Data are positive for up to 7 years, but what about 10 to 15 years? Up to 5 years of standard hormones for osteoporosis prevention makes sense, most especially in the symptomatic woman. After that a conversion would seem to be most appropriate.

My prediction at this time is that these hormones will remain a valuable component within our therapeutic armamentarium, with short-term (less than 5 years) use for specific indications presenting a favorable benefit-to-risk profile. In usual-age perimenopausal women (45 to 55), the prevalence of thromboembolism and coronary heart disease is low, risk of breast cancer with less than 5 years’ therapy appears to be nonsignificant, and symptomatic benefit considerable. This is even more true of women experiencing ovarian failure at an earlier age. Beyond age 55, and for specific problems such as increased cardiovascular or osteoporosis risk, all other options need to be considered, again taking the individual risk-to-benefit ratio into account.

We at *Menopause Management* will attempt to focus articles over the next several months on issues that are truly pertinent, even if controversial, and will try to present a balance between opposing views. Stay posted—there will be a number of scientific publications in the immediate future, and keeping current is going to be one of the biggest challenges of all.



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