



Dr. Wulf H. Utian has served as Editor-in-Chief of *Menopause Management* since its inception in 1988. Arthur H. Bill Professor Emeritus of Reproductive Biology and Obstetrics and Gynecology at Case Western Reserve University, he is President of Rapid Medical Research, headquartered in Cleveland, and is Consultant in Women's Health to the Cleveland Clinic Foundation. He is a Fellow of both the Royal and American Colleges of Obstetricians and Gynecologists, a Fellow of the International College of Surgeons, and a board-certified reproductive endocrinologist.

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.

Thoughts on Suffering and Dying—Or, is “Disease A” Really Equivalent to “Disease B”?

Most healthcare researchers, epidemiologists and clinicians tend to consider morbidity and mortality in cold, professional terms until they, themselves, become victims of illnesses involving disability and dying. This is appropriate if the facts they report are correct, are based on solid data and interpretation thereof, and are accurately incorporated into risk-benefit and cost-effective recommendations.

These facts then assist in providing guidance to individual patients regarding decision-making about various therapeutic options. Conversely, if the application of the data is not correct, the advice and recommendations to the patient may be inappropriate, and may lead to misinformation and potential therapeutic error. Moreover, personal bias also may intrude and may not necessarily be in the patient's best interest.

Clearly, the primary objective of medical research and subsequent healthcare delivery is to enhance quality and duration of life. For years, there have been excellent published mechanisms for incorporating changes in survival and morbidity into a single measure that reflects the trade-offs between them. These “quality-adjusted life years”, or QALYs, can be combined with healthcare costs to determine the cost-effectiveness of a therapy, or to rank several therapies.¹ Obviously, the available database on the effectiveness of most clinical procedures may be quite limited. Nonetheless, current analysis and decision-making must be based upon the best available current evidence.

Thus, the ideal measure of healthcare effectiveness of a particular clinical practice has to be outcome-oriented, and the ultimate measures are length and quality of life (QoL). The latter clearly involves subjective values, but can be measured as a “trade-off” between longevity and quality, the basic concept of the QALY. Postmenopausal hormone therapy (HT) lends itself well to this type of analysis.²

This entire concept has been largely ignored in the current debate over the use of postmenopausal pharmacotherapy. Any clinician who has spent time with patients suffering with various chronic diseases realizes that one disease is not equivalent to another. In this day and age, for example, it is far easier—medically and emotionally—on the majority of women to be treated for early-stage breast cancer than to be immobilized by severe backache following osteoporotic vertebral crush fractures. Were you to ask the woman with breast cancer how much life expectancy she would be prepared to trade in order to feel “well and active,” she would likely be prepared to relinquish little, saying that she feels perfectly well. In contrast, the woman with debilitating backache is likely to be willing to trade 5 years of life expectancy just to

be mobile and independent again. Similarly, it is patently absurd to equate a non-fatal heart attack with the stark reality of the irreversible and inexorable descent into the mental oblivion of Alzheimer's disease.

Each disease has outcomes that can be measured by subjective and objective values. Therefore, it is totally unacceptable in this day and age to report the outcome of any specific therapy with multiple potential positive and negative endpoints, such as heart attack, thrombosis, dementia and fracture, as if each of these were equivalent events. Yet, that is precisely how the Global Health Index has been utilized in the reports from the Women's Health Initiative (WHI).³ This non-validated index, based on the first occurrence of one of several predefined events, has been used by WHI investigators as the defining mechanism to balance the risks and benefits of HT, and to develop conclusions and recommendations for public health policy and clinical practice.

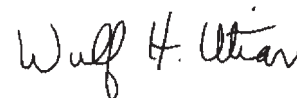
In the latest WHI report on HT and osteoporotic fracture,⁴ which is the only published study to prove efficacy in all-fracture reduction for a pharmacologic agent in a non-osteoporotic population, the authors temper the good news by concluding that "E + P increases BMD and reduces the risk of fracture in healthy postmenopausal women...when considering the effects of hormone therapy on other important disease outcomes in a global model, there was no net benefit, even in women considered to be at high risk for fracture."⁴

Suffering and death, or any measure of impact on QoL, were simply ignored. One case of breast cancer, in their opinion, is equal to one heart attack, which is equal to one fracture. This approach is simply not good enough in modern medicine.

As our healthcare system becomes more and more technologically, statistically, medicolegally and financially driven, it is inevitably moving in the opposite direction of real health "care". When we sacrifice "caring" about levels of suffering and disability, and base decisions solely on artificial indices such as the "Global Health Index" of the WHI, we compromise our right to be health "care" providers.

I cannot emphasize strongly enough that this criticism of current affairs must not be taken as a recommendation for or against the use of HT. The QoL and cost-effectiveness analyses are simply lacking. Rather, this is an urgent appeal for a more precise and humanitarian approach to data evaluation, so that advice given to women facing severe medical problems or making difficult medical decisions can be truly "quality"- and "caring"-based. For the clinician helping women to

enhance QoL, the challenge remains to recognize that each woman has a unique profile that needs to be recognized and utilized in medical management.



Wulf H. Utian, MD, PhD
*Executive Director and
Honorary Founding President
The North American Menopause Society*

References

1. Weinstein MC, Stason WB. Foundations of cost-effectiveness analysis for health and medical practices. *N Engl J Med* 1977;296:716-21.
2. Utian WH. Application of cost-effectiveness analysis to postmenopausal estrogen therapy. *Front Hormone Res* 1978;5:26-39.
3. Writing Group for the Women's Health Initiative Investigators. Risks and benefits of estrogen plus progestin in healthy postmenopausal women. *JAMA* 2002;288:321-33.
4. Cauley JA, Robbins J, Chen Z, et al. Effects of estrogen plus progestin on risk of fracture and bone mineral density: The Women's Health Initiative randomized trial. *JAMA* 2003;290:1729-38.