

# From the EDITOR



**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.

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## The Psychosocial and Socioeconomic Burden of Menopausal Vasomotor Symptoms

We are constantly informed of the high socioeconomic impact of a number of diseases, from osteoporotic fractures, to heart attacks, to various cancers. But disruptive symptoms like headache, backache—and yes, hot flashes—are also a source of considerable medical cost and socioeconomic impact. I recently reviewed the psychosocial and socioeconomic burden of menopausal vasomotor symptoms (VMS) elsewhere,<sup>1</sup> but in this column would like to draw your attention to some of the most significant conclusions of that review.

### The Impact of Hot Flashes

Recent US Census Bureau statistics indicate that approximately one-third of women living in the US are older than 50 years of age. It is estimated that 75% of women in this age group will experience hot flashes. Thus, in the United States alone, there are approximately 40- to 50-million women who experience hot flashes. The prevalence of hot flashes varies widely across populations and is strongly influenced by culture and ethnicity.

More recent findings have suggested that high body mass index and African-American race are associated with a higher risk of VMS. Smoking, maternal history, history of premenstrual complaints, elevated basal core body temperature, low physical activity and low socioeconomic status have all been associated with an increased risk of hot flashes.

VMS can have a significant negative impact on quality of life (QOL) in younger and older women, contributing to physical as

well as psychosocial impairment. Becoming flushed and sweating profusely in a social or work-related situation may cause extreme anxiety for many women, and may lead to social isolation.

Despite the lack of agreement in the medical literature about the relationship between VMS and sleep quality, mood variability, and cognitive function, these symptoms are, in fact, the primary complaints made by menopausal women to their healthcare practitioners.

The causes of menopause-related sleep disturbances are controversial. What is not controversial is the fact that inadequate and unrefreshing sleep can have many consequences. Over time, disruption of sleep secondary to hot flushes and/or night sweats leads to chronic sleep deficits, significantly impaired alertness and mental acuity, carelessness, forgetfulness, and decreased work productivity. In some cases, night sweats can drench bedclothes and sheets, further disrupting sleep and necessitating a change of clothes and covers, which can also disturb the sleep of the individual's bed partner. Thus, lack of sleep, tiredness, and irritability can affect daytime productivity as well as familial and social relationships.

### **Costs Associated with VMS and Their Treatment**

Determining the cost-effectiveness of treatments aimed at relieving VMS is complex. Analysis must consider the direct costs of treatment, costs associated with treatment-related adverse events and the healthcare costs saved with effective therapy. Cost-utility analysis of treatment for VMS also considers the impact of treatment on improvements in QOL associated with the alleviation of symptoms. This impact of treatment is expressed in quality-adjusted life years (QALYs).<sup>2</sup>

Before seeking medical advice upon the onset of VMS, women are likely to resort to self-diagnosis and treatment. They may combine over-the-counter drugs with medications prescribed for other conditions (eg, analgesics for headache; anxiolytics and anti-

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depressants for anxiety, tension and mood changes; sedatives/hypnotics for insomnia). Most of these treatments fail to provide significant relief of VMS.

Many women ultimately consult their physicians after these remedies fail. Costs incurred for the management of VMS include visits to physicians; follow-up visits and telephone calls for the management of medication-related side effects and changes in medication; self-prescribed over-the-counter remedies, including complementary alternative medications (CAMs); hormone therapy (HT); laboratory tests; lost productivity at work; personal costs for hygiene-related supplies; energy costs for the increased use of air conditioning; and extra laundry requirements for clothing and bed sheets soiled with sweat. The costs associated with many of these symptoms have not been quantified, but they undoubtedly result in a significant burden for the women who experience them.

All of these factors add to the economic burden of VMS.

### **Hormonal Therapy**

The economic burden of VMS management remains high even with the use of HT. Costs associated with HT include one or two visits for diagnosis and medication prescription as well as follow-up visits and telephone calls to manage side effects and evaluate the efficacy of therapy. Serious, but rare, adverse events associated with HT can lead to exceptionally high acute and chronic costs. Evaluation and

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management of more common transient adverse events, including vaginal and uterine bleeding, breast discomfort, and breast nodularity, can also add significantly to the overall cost of HT for menopause-related

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symptoms. Approximately one-third of patients who use HT switch to another form of therapy or make medication adjustments because of adverse events or compliance problems, increasing the overall cost of therapy.

### SSRIs and SNRIs

Selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRIs) have received increased attention for the management of VMS in non-depressed menopausal women. As yet, there is no research into any long-term risk associated with these drugs when prescribed to essentially healthy women. Nor have any pharmacoeconomic analyses of any agents in these classes been presented for this indication.

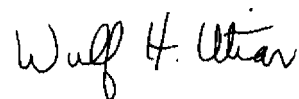
### Complementary and Alternative Medicines

Many symptomatic menopausal women are likely to treat themselves before consulting a medical practitioner, thinking that “natural” products are safer and the ingredients more pure than synthetic agents. The most common CAM treatments used are products containing individual and compounded formulas of herbs, isoflavones and dietary supplements that promise to alleviate

menopause-related hot flashes and night sweats, irritability, sleeplessness, mood swings, weight gain, headaches, insomnia, depression, menstrual irregularities, fatigue and loss of sexual desire. The initial cost of a single product can be substantial.

### Conclusions

Menopausal vasomotor symptoms are very common and can be associated with a high patient and societal burden. These symptoms result in high direct and indirect costs and significantly reduced QOL. Current treatments for VMS include HT, prescription medications developed for other indications, and CAM treatments. Short-term HT has been shown to be cost-effective for the management of VMS, but the publicity given the findings of the WHI has substantially decreased the use of these treatments. A significant unmet need remains for treatment options for menopausal vasomotor symptoms. It is hoped that the development of therapies specifically targeting VMS may provide high efficacy and reduced risk of serious and potentially costly adverse events, thus increasing the overall cost-effectiveness of therapy.



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