Menopause is a natural process that occurs in women’s lives as part of normal aging. Sounds like something the NWHN might say? Well, it’s now also the consensus of a National Institutes of Health (NIH) State of the Science Panel. In March, 2005, the NIH convened a panel of scientists to evaluate what we know, what we don’t know, and what we need to know about menopause. The panelists (and an audience of health professionals, women’s health activists, and scientists) heard research presentations and discussed the current state of scientific knowledge on menopause-related symptoms.

Later, the NIH issued a consensus statement outlining the panel’s assessment of the effectiveness of available treatments for menopause-related symptoms, and future directions in research and clinical practice to improve the quality of life for women in the menopausal transition. This article provides a condensed summary of the consensus statement; the panel’s full statement is available at: http://consensus.nih.gov/2005/2005MenopausalSymptomsSOS025html.htm

After a thorough consideration of the science and research in the field, the panelists clearly stated that menopause is a natural and normal stage in a woman’s life and not a disease or condition to be eliminated. Set against the medical community’s historical treatment of menopause as a disease and an estrogen deficiency to be corrected, the consensus statement holds promise for a new approach to helping women stay healthy as we age. Rather than viewing menopause as a diagnosis (and menopausal women as both estrogen “deficient” and in need of a prescription) providers may begin to recognize the diversity of menopause experiences and tailor their responses accordingly. In addition, the NIH statement may lead to additional studies and research to better understand the spectrum of women’s experiences during this life phase.

**NIH Panel Considered Five Major Questions**

The conference panelists explored five major questions to improve understanding of women’s experience of menopause, and rated the scientific evidence around these questions as “strong”, “moderate”, “limited” or “insufficient”, based on available
research. These terms were not applied consistently in the consensus statement; this article reflects the terminology used in the NIH document. This system enables both health care practitioners and women to differentiate between reliable, unreliable, and unavailable, science. The five questions, and the panel’s findings, were:

1. **What is the evidence that the symptoms more frequently reported by middle-aged women are attributable to ovarian aging and senescence [rather than to menopause]?**

Women experiencing the menopausal transition, as well as their health care providers, often wonder which symptoms or changes are attributable to aging generally, and which are caused by menopause. Symptom management to improve women’s health and quality of life is often better and more effective when the root cause of the problem is understood.

The panel found that strong scientific evidence suggests that the decline in estrogen levels that occurs with the menopausal transition is the cause of hot flashes and vaginal dryness: these changes are not simply due to general aging or mid-life changes. The scientific evidence linking sleep disturbance with menopause is only moderate, however. Difficulty sleeping may be age-related; sleep problems reported by women in the menopausal transition may be an indirect effect of hot flashes or other menopause-related symptoms.

Low or fluctuating moods have been reported by women in the menopausal transition. There is only limited evidence that ovarian changes associated with menopause itself are the root of the problem, however. A history of depression, life stress, and health status are better indicators of mood symptoms at mid-life. The panel found only weak evidence that estrogen pills are superior to placebo in treating mood symptoms during the menopausal transition.

Research indicates that the menopausal transition does not cause an increase in somatic symptoms such as back pain and stiff or painful joints. There is also insufficient scientific evidence that women’s reports of difficulty thinking, forgetfulness, or other cognitive disturbances are caused by the menopausal transition. Further research is essential to determine if changes in mental functioning reported by some women are caused by the menopausal transition or by other aging-related processes. There is also a need for more research to determine the relationship between the menopausal transition and urinary incontinence, uterine bleeding, and general quality of life.

Finally, extensive media attention has been paid to the loss of libido and problems with sexual function experienced by some women in the menopausal transition. Women’s own reports and studies of physiological changes during menopause indicate that thinning of the vaginal wall lining often results in painful sexual intercourse, and that this can subsequently affect a woman’s inclination for sexual activity. Yet, scientific evidence indicates that age-related changes (e.g., personal...
relationships, life stress, and socioeconomic conditions) are more likely to impact sexual health than physiological changes.

2. When do menopausal symptoms occur, how long do they persist and with what frequency and severity, and what is known about the factors that influence them?

Women themselves are often uncertain about when menopause begins, how long it lasts, and when the life stage ends. Part of this uncertainty stems from the fact that the criteria to define “menopause” are time-dependent. Perimenopause, when a woman’s body begins to transition into menopause, begins when menstrual cycles become variable. For most women who experience natural menopause, this can happen anywhere between ages 40--58. For women who experience early menopause, or surgical menopause induced by radiation, chemotherapy, or removal of the ovaries and uterus, onset can occur at even younger ages.

The panel found strong evidence that the start of the menopausal transition can be indicated either when an increase in follicle-stimulating hormone (FSH) accompanies variability in a woman’s menstrual cycles, or when a woman experiences 60 or more days without her period (usually two missed menstrual cycles). The final post-menopausal stage cannot be identified until 12 months have passed since a woman’s last period.

The frequency and severity of menopausal symptoms varies widely between women. Although some report no symptoms during menopausal transitions, others report debilitating episodes of hot flashes and insomnia. Estimates of the prevalence of menopause-related symptoms vary by age, severity, type of symptom, and by how the symptom is measured. Therefore, we still do not have a clear picture of how many women experience menopause-related symptoms or how severe the symptoms are. There have not been enough long-term scientific studies to truly describe what women can commonly expect from the menopausal transition. Hopefully, a large-scale longitudinal study of U.S. women currently underway will provide better understanding of these issues.

3. What is the evidence for the benefits and harms of commonly used interventions for relief of menopause-related symptoms?

The consensus statement noted that, while many treatments are currently available for menopause-related symptoms (especially hot flashes and vaginal discomfort), research on their efficacy is either inconclusive or not yet available.

Hormones have been a commonly used and traditional strategy to relieve hot flashes and vaginal dryness. The Women’s Health Initiative (WHI) was a longitudinal study of hormones’ effects on women’s health in 0.625 mg of conjugated equine estrogen was administered to participants to assess its effect on menopausal symptoms. This dose was found to increase women’s risk for serious disease events including heart attacks, stroke, breast cancer, blood clots, and dementia. As a result, the WHI abruptly stopped treating participants in July, 2002.
Based on the WHI findings, many health care practitioners have theorized that lower estrogen does would yield reduced risks, and drug companies have continued to market hormone products on this basis. Yet, there was a clear consensus among the NIH conference attendees that no scientific evidence suggests that lower doses of hormones are any less risky to a woman’s health than higher doses.

Given what we now know from the WHI, the risks and benefits of taking hormones should be carefully considered before a woman chooses this treatment for menopause-related symptoms. Since hormone therapy is an effective treatment for hot flashes and vaginal dryness, determining an individual woman’s risk-benefit ratio is critical.

The panel also noted that ‘natural’ or ‘bio-identical’ hormones are sold both over-the-counter and in compounding pharmacies. These products may contain hormones including: estrone, estradiol, estriol, DHEA, progesterone, pregnenolone, and testosterone. Unfortunately, there is a serious lack of scientific data on the risks or benefits of these products. Androgens, including testosterone, have also been used to treat menopause-related symptoms, yet the research on the benefits of doing so has been mixed. According to the NIH statement, long-term risks of testosterone use have not been studied in women at mid-life. Adverse effects of taking testosterone may include acne, heavy hair growth, and weight gain.

Antidepressants and other medications have shown some efficacy for treating hot flashes, but the long-term effects of these medications are still unknown. The panel found that clonidine is effective in reducing hot flashes, but only in breast cancer survivors.

In terms of ‘alternative’ treatments (i.e., botanicals and dietary supplements), there is often no standardized formulation or dose available, making it difficult to compare results across studies. Black cohosh, the most studied herb, has a good safety record, but there is little evidence that it is effective in treating hot flashes. Other botanicals that have been studied include: red clover leaf, dong quai root, and ginseng root. Preliminary evidence indicates that these treatments are not effective for hot flashes or other menopausal symptoms, but research on botanicals is still in its infancy.

Other approaches to treatment of menopausal symptoms (primarily hot flashes) include exercise, which improved quality of life but not menopausal symptoms, and paced respiration, a breathing technique that shows early promise in reducing hot flashes.

4. **What are the important considerations in managing menopause-related symptoms in women with clinical characteristics or circumstances that may complicate decision making?**

Every woman is unique; therefore, there is no one simple remedy that will quickly address all women’s health needs. Common factors that every woman can consider
when making a decision about how to manage her menopause-related symptoms include her medical history and personal risk factors. For example, a woman with a genetic predisposition to, or a history of, breast cancer; a family history of breast or ovarian cancer; or an increased risk for cardiovascular disease, increases her risk of these conditions if she takes hormone therapy. Under these circumstances, she may want to consider other medical, or non-medical, therapies for menopause-related symptoms.

5. **What are the future research directions for treatment of menopause-related symptoms and conditions?**

Panelists of the NIH conference agreed that it was essential to construct a conceptual framework to improve scientists’ understanding of women’s experience of menopause. The premise of this conceptual framework would be to view the menopausal transition holistically, rather than as disparate symptoms unrelated to systemic processes. Building this conceptual framework will necessitate conducting more scientific studies, over longer periods of time, and among more diverse groups of women. Further, research is needed that focuses on understanding self-care strategies that help women manage menopause-related symptoms; on the natural history of menopause in the 15–25 years after a woman’s final menstrual period; and on the long-term effects of low-dose hormone therapy. Other medical and non-medical therapies need to be studied to determine efficacy and safety profiles. Finally, women and their health care practitioners both need better tools to estimate an individual woman’s risk when using hormone therapy.

*Future Directions for the NWHN and Women’s Health Advocates*

In the coming months, the NWHN will be working on several fronts to continue raising awareness about menopause as a natural process, as well as advocating for public policy that respects women’s diverse needs as we age. These efforts will include an analysis of ongoing research studies of hormones in perimenopausal women to determine whether or not there is a compelling argument, based on the available science, for continuing to study hormone therapy in women in their 30’s and 40’s. We will also work with the FDA to ensure that compounding pharmacies that market and provide ‘natural’ or ‘bioidentical’ hormones directly to women are held to good manufacturing practices, sterility standards, and truthful marketing campaigns. The NWHN will continue to act as a voice in women’s health care and use the NIH consensus statement as a tool in these efforts.

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