News from Good Life

Thank you for entrusting in the compounding services at Good Life Pharmacies to help meet the unique medication needs of your patients. We are excited to share our monthly newsletter with you and look forward to continuing to be your medication problem solvers.

Be sure to visit our new website at **www.goodliferx.com.** You or your patients can contact us via our HIPAA-compliant forms and learn how compounding can provide solutions for your medication challenges.

Please don't hesitate to let us know how we can be of further assistance to you and your practice.

Sincerely,
Jim Andreesen, R.Ph.
Angie Svoboda, Pharm.D. FIACP
Ray Scott, R.Ph.

RETHINKING HORMONE REPLACEMENT

The North American Menopause Society (NAMS) released its 2017 Hormone Therapy Position Statement, which has been endorsed by 52 agencies including the American Association of Clinical Endocrinologists, the American Women's Medical Association, and the Society of Obstetricians and Gynaecologists of Canada, and supported as an educational tool by the American College of Obstetricians and Gynecologists (ACOG). To quote the statement: **"Hormone therapy (HT) remains the most effective treatment for vasomotor symptoms (VMS) and the genitourinary syndrome of menopause (GSM) and has been shown to prevent bone loss and fracture.** ***The risks of HT differ depending on type, dose, duration of use, route of administration, timing of initiation, and whether a progestogen is used. Treatment should be individualized to identify the most appropriate HT type, dose, formulation, route of administration, and duration of use, using the best available evidence to maximize benefits and minimize risks,*** **with periodic reevaluation of the benefits and risks of continuing or discontinuing HT. For women aged younger than 60 years or who are within 10 years of menopause onset and have no contraindications, the**

benefit-risk ratio is most favorable for treatment of bothersome VMS and for those at elevated risk for bone loss or fracture. For women who initiate HT more than 10 or 20 years from menopause onset or are aged 60 years or older, the benefit-risk ratio appears less favorable because of the greater absolute risks of coronary heart disease, stroke, venous thromboembolism, and dementia. Longer durations of therapy should be for documented indications such as persistent VMS or bone loss, with shared decision making and periodic reevaluation. For bothersome GSM symptoms not relieved with over-the-counter therapies and without indications for use of systemic HT, low-dose vaginal estrogen therapy or other therapies are recommended."

Findings from the Women's Health Initiative (WHI) published in 2002 indicated a greater risk of breast cancer and coronary heart disease among women who used a combination of estrogen and progestin as menopausal hormone replacement therapy. In the WHI study arm that investigated the use of estrogen alone (no progestin in women who had hysterectomies), there was a decrease in the risk of breast cancer and heart disease, and a lower rate of mortality in comparison with women who received a placebo.

The backlash from these widely publicized findings frightened many women and some physicians, and the use of hormone replacement therapy precipitously declined. Sarrel et al. of the Yale University School of Medicine, Yale University School of Public Health and University of Florence (Italy) Department of Public Health examined the effect of estrogen avoidance on mortality rates. They derived a formula to relate the excess mortality among hysterectomized women aged 50 to 59 years assigned to placebo in the WHI randomized controlled trial to the entire population of comparable women in the United States, incorporating the decline in estrogen use observed between 2002 and 2011. They calculated that a **minimum of 18,601 and as many as 91,610 postmenopausal women died prematurely because of the avoidance of estrogen therapy.** "Sadly, the media, women, and health care providers did not appreciate the difference between the two kinds of hormone therapy," commented lead researcher Philip Sarrel, MD. "As a result, the use of all forms of FDA-approved menopausal hormone therapy declined precipitously." He concluded that informed discussion between the women and their health care providers about the effects of hormone therapy is a matter of considerable urgency. "Essentially, estradiol inhibits the development of atherosclerosis and helps maintain normal arterial blood flow."

In September, 2017, Manson et al. published an observational follow-up of approximately 98% of the 27,347 postmenopausal women aged 50-79 who were enrolled in two WHI randomized clinical trials between 1993 and 1998 and followed up through 2014. They concluded that among postmenopausal women, hormone therapy with estrogen plus progestin for a median of 5.6 years or with estrogen alone for a median of 7.2 years was not associated with risk of all-cause, cardiovascular, or cancer mortality during a cumulative follow-up of 18 years.

Evidence indeed shows that natural progesterone displays a favorable action on the vessels and on the brain, while this might not be true for some synthetic progestins. Compelling indications exist that differences might also be present for the risk of developing breast cancer, with trials indicating that **the association of natural progesterone with estrogens confers less or even no risk of breast cancer as opposed to the use of synthetic progestins.**

In September 2017, Arefa Cassoobhoy, MD, MPH, a senior medical correspondent for Medscape, interviewed JoAnn Manson, MD, professor of medicine at Harvard Medical School and Brigham and Women's Hospital in Boston, and lead author of the WHI. Dr. Manson shared the following perspectives:

- For women (below age 60) and closer proximity to onset of menopause (within 10 years), the absolute risks of heart disease, stroke, deep venous thrombosis (DVT), and breast cancer, related to hormone therapy, are lower.
- Women who are at greater risk for and have a higher frequency of hot flashes and night sweats are more likely to derive quality-of-life benefits from hormone therapy. Thus, the benefit-risk ratio becomes much better because of the lower absolute risk and the greater likelihood of deriving quality-of-life benefits.
- Transdermal hormone therapy has the advantage of avoiding first-pass liver metabolism, and therefore it's

less likely to increase clotting protein or triglyceride levels and avoids some of the other concerns associated with the oral route of administration. The observational studies suggest that the risks for DVT, pulmonary embolism, and possibly even stroke are lower with the transdermal than the oral route. As of yet, there are no large-scale randomized trials doing direct head-to-head comparisons.

- The risk for cardiovascular events, both heart disease and stroke, will be greater in older women. If you are going to use hormone therapy in women who are more distant from the onset of menopause or who have significant risk factors such as diabetes or hypertension, it is preferable to go with the low-dose transdermal formulation rather than oral hormone therapy.
- In contrast to the vasomotor symptoms (hot flashes and night sweats), genitourinary symptoms actually progress over time. About 50% of women are seriously affected by these symptoms in terms of decreased quality of life, poor sexual health, and discomfort with sexual activity. Genitourinary conditions and also are associated with urinary tract infections and physical health. These symptoms are undertreated and under-recognized, and clinicians should ask about them because many women are very uncomfortable bringing up the subject. Low-dose vaginal estrogen is the most effective treatment and does not increase the blood level of estrogen above the usual postmenopausal range. In terms of the evidence base and the clinical trial data, there is no evidence of an increased risk for heart disease, stroke, DVT, dementia, or breast cancer with low-dose vaginal estrogen.
- Women with early menopause (either premature ovarian insufficiency or early surgical menopause)-who have an increased risk for heart disease, cognitive decline, bone loss, and osteoporosis - are particularly good candidates for hormone therapy.
- The WHI observational follow-up urges caution when considering initiating hormone therapy at an older age in women with diabetes, as these women are at the greatest risk for cognitive decline.

Menopause. 2017; 24(7):728-753
Am J Public Health. 2013 Sep; 103(9):1583-8.
JAMA. 2017 Sep 12; 318(10):927-938.
Maturitas. 2008; 60:185-201.
NAMS' New Hormone Therapy Position Statement: Clinical Takeaways - Medscape - Aug 15, 2017.

NOTES:

- Before initiating hormone therapy, it's important to check baseline levels, and to monitor levels during therapy. Convenient, inexpensive home testing is available. Blood spot or saliva testing can be recommended based on the hormones being checked, and if oral or transdermal therapy is used.
- Our compounding pharmacy puts patient safety first by adhering to current regulations and compounding medications using pure ingredients from FDA-inspected facilities.

REASONS FOR CHOOSING COMPOUNDED MEDICATIONS INCLUDE:

- Patient allergies or failure to respond to commercial products
- Adverse reactions to commercial preparations; i.e., if a patient has a reaction to an adhesive on a patch, we can compound the needed medication as a transdermal cream.
- Need for a dose or dosage form that is not commercially available. For example, transdermal and vaginal creams may offer potential advantages because non-oral administration bypasses first-pass hepatic metabolism.

Our pharmacist will work with you to compound medications that will best meet your patients' specific needs.

READ MORE ABOUT HORMONE THERAPY FOR WOMEN

Hormone Consultation
by Angie Svoboda, Pharm.D.

Have your hormone levels and symptoms evaluated by Angie Svoboda, Pharm.D. Dr. Svoboda has been working with hormone replacement for men and women for over 20 years. Consults can be via telephone.

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