iv. Lower doses of oral estrogens may be safer in terms of VTE risk than higher doses
v. Not recommended for primary or secondary prevention of stroke
vi. Not recommended for women with elevated baseline of stroke

Source: March 2007 position statement of The North American Menopause Society

B. NAMS Guidelines related to Depression, Dementia, Cognitive Decline

i. Evidence currently does not support use of ET/EPT for depression treatment (although NAMS recognizes studies showing benefits of ET for depression during peri-menopause)
ii. Initiating EPT after age 65 for primary prevention of dementia or cognitive decline may increase risk of dementia during ensuing 5 years
iii. Evidence insufficient to support or refute efficacy or harm of ET/EPT for primary prevention of dementia when initiated during the menopause transition or early postmenopause
iv. ET does not appear to convey a direct benefit or harm for treatment of dementia due to Alzheimer's disease

Source: March 2007 position statement of The North American Menopause Society

C. NAMS Guidelines related to Osteoporosis

i. There is strong evidence of the efficacy of ET/EPT in reducing the risk of postmenopausal osteoporotic fracture
ii. ET/EPT can be considered an option for women requiring drug therapy for osteoporosis risk reduction

Source: March 2007 position statement of The North American Menopause Society. Menopause. 2007;14(2):168-182.

D. NAMS Guidelines related to Breast Cancer Risk of HT

i. Estrogen alone for < 5 years has little impact on breast cancer risk
ii. ET for > 15 years may increase risk of breast cancer (based on limited observational data)
iii. Minimal data reports any change in breast cancer mortality with HT
iv. EPT and, to a lesser extend, ET, increase breast cell proliferation, breast pain, and mammographic density
v. EPT may impede the diagnostic interpretation of mammograms

Source: Recommendations for estrogen and progestogen use in peri-and postmenopausal women: March 2007 position statement of The North American Menopause Society. Menopause. 2007;14(2):168-182.

E. NAMS Guidelines related to Progesterone

i. Only for endometrial protection from unopposed ET in women with intact uterus
ii. Postmenopausal women without uterus should not be prescribed progestogen with systemic estrogen
iii. Progestogen generally not indicated with low-dose, locally administered estrogen for vaginal atrophy
iv. No evidence to recommend off-label use of long-cycle progestogen, vaginal administration of progesterone, the levonorgestrel-releasing IUD (Mirena), or low-dose estrogen without progestogen as alternative to standard HT regimens

Source: Recommendations for estrogen and progestogen use in peri-and postmenopausal women: March 2007 position statement of The North American Menopause Society. Menopause. 2007;14(2):168-182.

F. ACOG Recommendation related to HT

i. Counsel women that although WHI findings indicate estrogen/progestogen is associated with increased risk of breast cancer, the absolute risk for any individual woman remains low
ii. Women taking estrogen only need to consider other risk factors, including heart disease, VTE, and stroke
iii. Breast cancer survivors should consider alternatives to HT for treating menopausal symptoms

Source: ACOG Task Force on HT. Obstet Gynecol. 2004;104(suppl 4):106s-17s.

G. USPTFS Recommendations

i. Recommends:
   1. Clinicians should use a shared decision-making approach to preventing chronic diseases in perimenopausal and postmenopausal women
   2. The USPSTF did not consider the use of hormone therapy for managing menopausal symptoms.
   3. Women and their clinicians should discuss the balance of risks and benefits before deciding to initiate or continue hormone therapy for menopausal symptoms.
ii. Recommends against:
   1. The use of EPT for the prevention of chronic conditions in postmenopausal women
   2. Routine use of unopposed estrogen for prevention of chronic conditions in postmenopausal women who have had a hysterectomy

Source: Hormone therapy for the prevention of chronic conditions in postmenopausal women: recommendations from the U.S. Preventive Services Task Force. Ann Intern Med 2005 May 17;142(10):855-60.

10. Promotion of bio-identical hormones by celebrities and news reports surrounding HT has made discussing symptom management with my peri-menopausal and menopausal patients easier.

It is important to help your patients understand that these compounds have exactly the same chemical and molecular structure as hormones produced in the body, and that little evidence supports the perception of greater safety with bio-identical hormones. There is also no evidence that the results of the WHI were related to the molecular structure of the synthesized hormones or that customized or different hormone doses would have changed the outcomes. Finally, they should understand that many formulations of these hormones are not subject to FDA oversight and may be inconsistent in purity and dosage.

Source: North American Menopause Society. Recommendations for estrogen and progestogen use in peri-and postmenopausal women: March 2007 position statement of The North American Menopause Society. Menopause. 2007;14(2):168-182.

menopause

mood swings

hot flashes

low sex drive

night sweats

problem sleeping

irregular periods

weight gain

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menopause face II face

University of North Texas Health Science Center
Professional and Continuing Education

Clinical Information Related to Menopause Self Assessment

1. My comfort level related to prescribing hormone therapy (HT) to my peri-menopausal patients is high.

Although guidelines have been established and recognized by highly reputable private and public organizations, concerns over the Women's Health Initiative (WHI) and HT persist, especially in primary care where physicians are almost half as likely to support the use of HT as are gynecologists. Gynecologists, in turn, are only half as likely to support HT than they were pre-WHI.

Sources:

a. Brett AS, Carney PI, McKeown RE. Brief report: attitudes toward hormone therapy after the Women's Health Initiative: a comparison of internists and gynecologists. J Gen Intern Med. 2005 May;20(5):416-8.

b. Power ML, Zinberg S, Schulkin J. A survey of obstetrician-gynecologists concerning practice patterns and attitudes toward hormone therapy. Menopause 2006;13:434-441.

2. Most of my peri-menopausal patients are prescribed hormone therapy.

Data show many physicians inconsistently follow menopausal symptom management and HT recommendations of reputable organizations, perpetuated by the complexity of the material and rapidly changing information. In general, primary care physicians are prescribing inappropriate therapies, providing incomplete advice or simply failing to address all of their female patients' questions and concerns about menopause and treatment options for associated symptoms.

Source: Roumie CL, Grogan EL, Falbe W, Awad J, Speroff T, Dittus RS, Elasy TA. A three-part intervention to change the use of hormone replacement therapy in response to new evidence. Ann Intern Med. 2004 Jul 20;141(2):118-25.

3. My comfort level related to prescribing alternative non-HT treatment for menopausal symptoms is high.

In recent years, information about HT has manifested in the form of incomplete or questionable news and (more recently) web articles on studies, benefits and risks of HT for menopause-related symptoms. Physicians are also forced to look beyond traditional therapies, based largely on patient treatment choices and requests. For example, non-hormonal and alternative therapies have become increasingly popular and are quickly approaching the level of use of HT for menopausal symptoms.

Non-HT prescription drugs including anticonvulsant gabapentin, antihypertensive clonidine and antidepressants may have benefits for some menopausal women, especially in patients who have no specific contraindications. Gabapentin and clonidine have even been evaluated in clinical trials for vasomotor symptoms with some success. Somnolence, fatigue, dizziness, rash, heart palpitations and peripheral edema were reported with gabapentin use. Adverse effects with clonidine may include dry mouth, insomnia or drowsiness. It is important when prescribing gabapentin to titrate the dose slowly to improve efficacy while reducing the incidence of adverse effects.

Sources:

a. Ma J, Drieling R, Stafford RS. US women desire greater professional guidance on hormone and alternative therapies for menopause symptom management. Menopause. 2006 May-Jun;13(3):506-16.

b. Nelson HD, Vesco KK, Haney E, et al. Nonhormonal therapies for menopausal hot flashes: systematic review and meta-analysis. JAMA. 2006;295(17):2057-2071.

c. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of menopause. Endocr Pract. 2006;12(3):315-337.

4. I consistently initiate discussions about menopause and menopausal symptom management to my peri-menopausal patients during routine exams.

Complicating matters for primary care physicians and patients, women feel reluctant to discuss HT and menopause with their providers. In fact, one study noted that almost half of women [in the study] left the physician's office with unanswered questions about HT and menopause, with almost two-thirds indicating that HT was not ever discussed in their appointment. Similar clinical challenges are experienced by younger physicians, who generally feel their knowledge of HT is insufficient and are unprepared to counsel women about HT. This statement is supported by Hess, et al., who found that "fewer than one-half of [resident physicians] are knowledgeable…about the rapidly changing field of HT and menopause management and that fewer than one third of residents feel adequately prepared to counsel women about it." Hess also points out that experiential learning, rather than sporadic didactic instruction, increases knowledge and comfort with HT and menopause issues.

Sources:

a. Clinkingbeard C, Minton BA, Davis J, McDermott K. Women's knowledge about menopause, hormone replacement therapy (HRT), and interactions with healthcare providers: an exploratory study. J Womens Health Gend Based Med. 1999 Oct;8(8):1097-102.

b. Hess R, Chang CC, Conigliaro J, Elnicki DM, McNeil M. Experiential learning influences residents' knowledge about hormone replacement therapy. Teach Learn Med. 2004 Summer; 16(3):240-6.

5. I try to accommodate a patient's request for specific therapy related to menopausal symptoms even if I am not familiar with that treatment.

The goal is for you and your patients to arrive at shared decision making, where you work together to assess available options for treatment and the risks and benefits of each option. Studies find that only a fraction of patient/physician discussions address the pros and cons of alternatives for medical treatments, and/or the uncertainties associated with them. Both of these issues are particularly important in discussions around menopausal therapies, since many women today choose to use complementary and alternative therapies, often with very little information about their potential risks and benefits.

Sources:

a. Braddock CH, 3rd, Fihn SD, Levinson W, Jonsen AR, Pearlman RA. How doctors and patients discuss routine clinical decisions. Informed decision making in the outpatient setting. J Gen Intern Med. 1997;12(6):339-345.

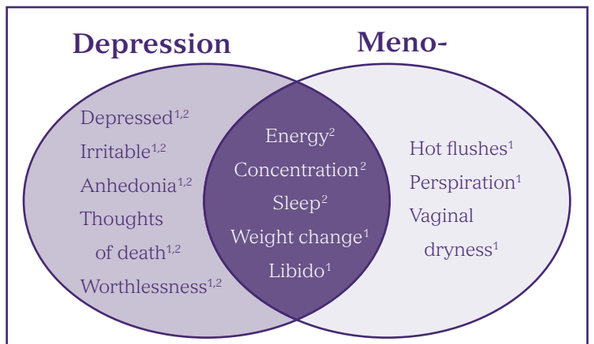
b. Brett KM, Keenan NL. Complementary and alternative medicine use among midlife women for reasons including menopause in the United States: 2002. Menopause. 2007;14(2):300-307.

c. Armitage GD, Suter E, Verhoef MJ, Bockmuehl C, Bobey M. Women's needs for CAM information to manage menopausal symptoms. Climacteric. 2007;10(3):215-224.

6. I am comfortable assessing the psycho-social factors of menopause.

The incidence of depression during the menopausal transition remains variable, likely due to variability within studies. Some populations come from menopausal clinics, which are more likely to attract patients with severe symptoms; others are community-based. The studies also vary in their definition of "menopause" and menopausal transition, basing definitions on a variety of factors including age, hormonal status, symptomatology, or menstrual cycle irregularities. Some studies are retrospective, others prospective. More recent studies, however, point to a significantly increased risk of major depression in peri-menopausal women.

One of the largest such studies is the Study of Women's Health Across the Nation (SWAN), which found the menopausal transition to be associated with an increased risk of depression. In SWAN, women in the early or late stages of peri-menopause had the highest risk of depression. The risk of depression was also highest in the early stage of postmenopause, or in women using hormone therapy compared to pre-menopausal women.



1. Soares CN, Cohen LS. CNS Spectrums. 2001;167-174.

2. Joffe H, et al. Psychiatr Clin North Am. 2003;26:563-580.

Women were also more likely to have clinical depression in the late peri-menopausal stage compared to the early stage. These risks appeared in women who were currently using HT or had used HT in the past, and were high even in women with a low risk of pre-menopausal depression.

When diagnosing depression in menopausal women, it is important to be aware of the symptoms of menopause and depression and of where they overlap. As this diagram shows, the two sets of symptomatology overlap significantly in areas of energy, concentration, sleep, weight change, and libido.

Sources:

a.Cohen LS, et al. Diagnosis and management of mood disorders during the menopausal transition. Am J Med. 2005;118 Suppl 12B:93-97.

b. Bromberger JT et al. Depressive symptoms during the menopausal transition: The Study of Women's Health Across the Nation (SWAN). J Affect Disord. 2007

c. Soares CN, Cohen LS. CNS Spectrums. 2001;167-174.

d. Joffe H, et al. Psychiatr Clin North Am. 2003;26:563-580.

7. I am comfortable assessing the somatic symptoms of menopause.

Treatment of vasomotor and other somatic symptoms has undergone a paradigm shift since the WHI report in 2002. Prior to the report, HT was a mainstay in treating VMS and considered safe by many physicians an d their patients. However, in the days, weeks and months following the Women's Health Initiative, a flurry of media reports created confusion and concern among women using HT and physicians who prescribe HT. The overall message from media sources was that HT did more harm than good and the risks of increased breast cancer rates and cardiovascular concerns outweighed the benefits to women experiencing the menopausal and vasomotor symptoms. As a result of these safety concerns, the use of HT since WHI has dramatically decreased. As many as two-thirds of women stopped HT, becoming highly symptomatic. These concerns persist, especially in primary care where physicians are almost half as likely to support the use of HT as are gynecologists and gynecologist are only half as likely to support HT than they were pre-WHI, although guidelines have been established and recognized by highly reputable private and public organizations. Consequently, inappropriate therapies are prescribed or physicians simply fail to address the issue with patients, resulting in women whose symptoms go untreated.

Sources:

a. The Writing Group for the Women's Health Initiative. Risks and benefits of estrogen plus progestin in healthy postmenopausal women: principal results from the Women's Health Initiative randomized controlled trial. JAMA 2002;288:321–33.

b. Reid RL. Hormone therapy: the Women's Health Initiative has caused confusion and concern. Fertility and Sterility, vol. 80, no. 3, September 2003.

c. Reid RL. Translating the latest scientific advances into clinical practice. JOGC 2002;24:771–4.

d. Alexander IM, Moore A. Treating vasomotor symptoms of menopause: The nurse practitioner's perspective. J Am Acad Nurse Pract. 2007 Mar;19(3):152-63.

e. French LM, Smith MA, Holtrop JS, Holmes-Rovner M. Hormone therapy after the Women's Health Initiative: a qualitative study. BMC Fam Pract. 2006 Oct 23;7:61

f. Brett AS, Carney PI, McKeown RE. Brief report: attitudes toward hormone therapy after the Women's Health Initiative: a comparison of internists and gynecologists. J Gen Intern Med. 2005 May;20(5):416-8.

g. Power ML, Zinberg S, Schulkin J. A survey of obstetrician-gynecologists concerning practice patterns and attitudes toward hormone therapy. Menopause 2006;13:434-441.

8. I am familiar with most recent data related to HT in peri-menopausal and menopausal patients.

A recent article from the New England Journal of Medicine and subsequent media reports will no doubt further impair communication between primary care physicians and their patients. The article, by Manson, et al., highlights a 60% lower risk of severe coronary artery calcium (a major risk factor for heart attacks) in women who regularly use estrogen. [17]. News reports following the article pointed out significant flaws with the WHI, along with misleading and incorrect conclusions made in the final report. [18]

Sources:

a. Manson JE, et al. Estrogen therapy and coronary-artery calcification. N Engl J Med. 2007 Jun 21;356(25):2591-602.

b. Parker-Pope, Tara. How NIH Misread Hormone Study in 2002. The Wall Street Journal. July 9, 2007; Page B1.

9. My daily schedule allows me to stay current on new studies and findings related to HT.

A. <u>NAMS Guidelines: ET and EPT recommended for:</u>

i. Moderate-to-severe vasomotor symptoms

ii. Moderate-to-severe symptoms of vulvar and vaginal atrophy

1. Offer vaginal, not systemic HT if vaginal symptoms only indication

iii. Not recommended as single or primary indication for coronary protection in women of any age

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