Guidelines for Counseling Women on the Management of Menopause

By the Jacobs Institute of Women's Health Expert Panel on Menopause Counseling

Produced in Collaboration with The National Committee for Quality Assurance, The American College of Obstetricians and Gynecologists, and The North American Menopause Society
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INTRODUCTION

These guidelines are intended to assist clinicians (physicians, advanced practice nurses, health educators and others) and health plans in providing comprehensive counseling to women about managing menopause. The guidelines also specifically address the elements of counseling that are assessed in a new measure in the Health Plan Employer Data and Information Set (HEDIS). In HEDIS 2000, the National Committee for Quality Assurance introduced the Management of Menopause measure. This survey measure, the first in HEDIS's Informed Health Care Choices domain, evaluates the provision of counseling on managing perimenopausal and postmenopausal hormone changes to women age 47 to 55, during the past two years or ever, by their managed care organization.

The measure is scored as a composite of three components: exposure (whether and when counseling occurred); breadth (whether the counseling included information on the risks, benefits, and alternatives to hormone replacement therapy [ERT/HRT]), and personalization (whether the counseling involved consideration of the woman's personal and family medical histories and her own concerns). In order to achieve the maximum score, plans must demonstrate that this level of counseling was provided within the last two years. The measure does not assess the decisions the woman makes.

The HEDIS Management of Menopause measure was designed to determine whether health plans and/or their clinicians have provided at least adequate counseling, not necessarily optimal counseling. We believe that most health plans and clinicians will want to go beyond the minimum. This set of guidelines indicates what may be necessary to fulfill the HEDIS requirements, but it also makes further recommendations about how clinicians and health plans can provide the most complete counseling to perimenopausal and postmenopausal women. Ongoing clinical research continues to expand our understanding of the effectiveness and safety of existing therapies and preventive strategies for perimenopausal and menopausal women, and new treatments are being introduced as well. These guidelines are based on existing evidence, but clinicians will need to continually update their knowledge in this area, and we include recommendations on how they can do so. The guidelines do not recommend specific treatments.

Notes:

· Scientific definitions for menopause-related terminology are included in the Glossary. Since many of the issues we address in this document pertain to both perimenopausal and postmenopausal women, and since menopause can only be determined retrospectively, we use the term "menopausal" to refer to women for whom the HEDIS measure is intended. When necessary (e.g., when discussing vaginal dryness, which is more likely to occur after the menopause), we distinguish between perimenopausal and postmenopausal women.
· Managed care organizations wishing to implement the HEDIS Management of Menopause measure must obtain the technical specifications for the measure, which can be ordered from NCQA by calling 1-800-839-6487.

Document Structure

The focus of this document is on counseling women about the hormonal changes that occur at menopause, the effects of these changes, and ways to prevent and treat conditions associated with menopause and aging. For ease of use, it is divided into the following sections:

- Counseling Women about Menopause defines counseling and provides suggestions for clinicians and health plans that may help them to optimize menopause counseling.
- Resources for Women is a list of patient education and decision-making tools that women may find useful as supplements to their discussions with their clinicians.
- Facts about the Typical Perimenopause/Menopause Experience and Checklist of Topics to Cover in Counseling are intended to serve as guides for clinicians on the key items in menopause counseling.
- Managing Menopause discusses items on the Checklist (menopausal symptoms and diseases of advancing age along with management strategies) in greater detail and references the relevant medical literature.
- Resources for Clinicians and Health Plan Quality Managers provides sources of information that will keep practitioners up-to-date as the scientific understanding of menopause and relevant interventions evolve.

Glossary defines terms used in this document.

References contains all items referenced numerically in the document.

Bibliography lists all sources (other than those listed in References) that were used by the Panel and Jacobs staff for background information.

COUNSELING WOMEN ABOUT MENOPAUSE

Providing Personalized Menopause Counseling

Face-to-face contact between a patient and clinician may be what most commonly comes to mind when one thinks of "patient counseling." However, there are many methods of providing information to patients, such as classes or support groups, print materials, audio and videotape decision-making tools, telephone resource lines, and Internet tools.

In the HEDIS Management of Menopause measure, counseling refers to communication of information to assist a woman in making informed decisions about her health. In the context of the measure, counseling is not limited to a face-to-face encounter, but includes all information the patient received from her clinician(s) or health plan. It is likely that one or more face-to-face encounters will be required to assist the woman in personalizing the information she has received.

The HEDIS survey measure is designed to determine whether some type of counseling occurred, and if so, what components were included. Respondents are asked whether they were given any information about menopause by their clinician(s) or health plan. If so, they are asked if they were told about the potential benefits and risks of ERT/HRT and about alternative therapies or approaches to disease prevention and menopausal symptom relief. In addition, the survey asks about personalization of this information, i.e., did the counseling take into account the woman's medical history, family history, values, preferences, and concerns? Respondents are also queried about whether they had a chance to ask all of their questions.

The objectives of counseling include addressing women's questions and concerns, providing patient education, facilitating informed decision making, and enhancing the patient's confidence in the decision made and in her ability to carry it out or modify it over time. A partnership between clinician and patient characterized by mutual respect and trust enhances counseling. If a therapy is chosen, the patient and clinician should agree on the goals, whether they are short-term (menopause symptom relief), long-term (primary or secondary prevention of diseases associated with aging), or both. The clinician should re-visit decisions about menopause management with the patient at subsequent visits, as new research is published and the woman's health status and preferences may change over time. For instance, a woman who begins taking ERT/HRT to help with the symptoms of menopause will later need to evaluate the risks and benefits of long-term continuation.

Continuing therapy is another key issue in the management of menopause. The woman may experience troublesome side effects from pharmacologic agents, or fail to experience the expected or desired results. If the treatment decision was one made in partnership with her clinician, a woman is more likely to consult with the clinician before changing or discontinuing her treatment plan.

Designing an Approach for Menopause Counseling

Suggestions for Clinicians

- Make an effort to address all of the patient's questions, including those about therapies you would not recommend. Treat the woman's questions respectfully, even if her facts or sources are not ones you endorse.
- Ensure that the scientific information presented to the patient is objective. Achieve balance in presenting options, i.e., be aware of any biases you may have.
- Educate the woman about relevant health conditions (such as heart disease and osteoporosis) so she appreciates how these diseases could affect her quality of life in the future.
- Discuss the known risks and benefits associated with each option, and present in lay terminology information about the strength of the existing evidence and what remains unknown.
- Personalize the discussions based on the woman's health, social history, and family history.
- Consider the patient's preferences, values, and key concerns (e.g., family members' experiences, concern about breast cancer, etc.).
- Tailor the use of materials to the needs and wants of the woman. For example, some patients may want to read key scientific studies while others may prefer concise booklets that briefly summarize relevant information. Consider using high-quality decision-making tools and educational materials and programs to enhance the office visit counseling session.
- Consider with the woman practical issues that she may face if medication will be part of her management plan, such as cost, convenience, and side effects that might affect her desire to continue therapy.
- Ensure that follow-up is routinely done with all patients who start a treatment regimen. The interval for follow-up depends on the patient's needs and concerns.

Suggestions for Managed Care Organizations

- Scientific studies show that physicians' opinions about treatment options remain key determinants in clinical decision-making in general. This suggests that developing tools to assist not only patients, but also physicians, in keeping up-to-date on the facts and issues should improve the quality of clinical decision-making for women entering the menopause. (See the Resources for Clinicians section.)
- Health plans should provide education to clinicians about the collaborative decision-making approach and about the important components of counseling. (See relevant articles, marked with an asterisk, in the Bibliography, particularly Roter et al., 1997 and Strull et al., 1984.)
- Constraints on time for office visits has been cited by primary care doctors as an important barrier to providing comprehensive counseling to patients at the time of menopause. While providing for longer physician office visits might be an ideal approach, offering visits with non-physician clinicians as well as providing educational programs and materials in conjunction with visits may be a more realistic one.
- Given the proliferation of medical information available to consumers in general, it is important for health plans to direct their members to sources of objective information, or to make high-quality educational programs/decision-tools available to their members.

For more information on counseling and shared decision making, see citations in the Bibliography marked with an asterisk.

Resources For Women

Women and their clinicians may find the following patient education and decision-making tools helpful.*

Available from the American College of Obstetricians and Gynecologists - Resource Center
202-863-2518 or e-mail resources@acog.org
www.acog.org

Patient Information Brochures:
The Menopause Years
Midlife Transitions: A Guide to Approaching Menopause
Preventing Osteoporosis
Hormone Replacement Therapy

Available from The North American Menopause Society
www.menopause.org
Menopause Guidebook (also on Web site; Braille version available as well)
Induced Menopause Guidebook
Menopause: A New Beginning (5th-grade reading level)
Suggested Reading List (also on Web site)
"MenoPak" (packet available by calling 800-774-5342; $5 shipping fee)
The NAMS Web site has an extensive list of frequently asked questions (and answers) about menopause.

Developed by the Foundation for Informed Medical Decision-Making and available from Health Dialog, Inc.
1-888-289-7525
www.healthdialog.com
Treatment Choices for Hormone Replacement Therapy: A Shared Decision-Making Program (videotape)

Available from the Ottawa Health Decision Centre
613-798-5555
e-mail: ldrake@civich.ottawa.on.ca
Making Choices: Hormones After Menopause
A decision tool that consists of practitioner's manual and an audiotape, booklet, and worksheet for women

Available from the American Academy of Family Physicians
1-800-944-0000
Menopause: What to Expect When Your Body is Changing
Osteoporosis in Women: Keeping Your Bones Healthy and Strong

Available from the National Osteoporosis Foundation
Fax: 202-223-2237

www.nof.org
Boning up on Osteoporosis: A Guide to Prevention and Treatment
Be BoneWise Exercise: NOF's Official Exercise Video
How Strong are Your Bones?
Style Wise: A Fashion Guide for Women with Osteoporosis
(see Web site or fax inquiry for a complete list of titles)

Available from the National Women's Health Network
202-347-1140
www.womenshealthnetwork.org
Taking Hormones and Women's Health: Choices, Risks and Benefits
Available from Montreal Health Press
514-282-1171
Menopause Handbook

Available at bookstores
Our Bodies, Ourselves for the New Century: A Book by and for Women. Boston Women's Health Book Collective, Jane Pincus (Introduction). 1998.
The New Ourselves, Growing Older by Paula B. Doress-Worters and Diana Laskin Siegal, in Cooperation with the Boston Women's Health Book Collective. 1994.

The Office on Women's Health within the U.S. Department of Health and Human Services has compiled an extensive Menopause Resource Guide on their Web site that includes contact information for relevant federal agencies and organizations, as well as newsletters, magazines, reports and books.
www.4woman.gov/owh/pub/menoguide.htm

Soon to be available from the Comprehensive Health Enhancement and Support System (CHESS)
206-616-9250
Menopause and Beyond: Getting Answers, Making Choices. This computer-based education and support program includes a decision tool and a system through which users can send questions to other women and experts and receive personal answers. CHESS is a joint development between the University of Wisconsin-Madison, Center for Health Systems Research and Analysis and the University of Washington Department of Family Medicine and School of Nursing.

Soon to be available from Group Health Cooperative of Puget Sound
206-287-2927
To Be or Not to Be on Hormone Replacement Therapy: A Workbook to Help You Explore Your Options. This decision tool is a 30-page booklet containing information and self assessments for menopause, HRT use, breast cancer, heart disease and fracture. It was developed specifically for use in managed care organizations or other primary care settings to prepare women to have a meaningful discussion about HRT with their clinicians.

*The panel is not endorsing the use of the materials listed nor recommending against the use of any not listed; these were resources that the panel was aware of at the time of publication.

Facts About The Typical Perimenopause/Menopause Experience

- Average age at menopause is 51 (over 90% by age 55)
- Most women begin transition (perimenopause) at about age 47
- Perimenopause usually lasts 4-5 years, but may last only 2 years
- Perimenopausal changes:
  - change in amount or duration of menstrual flow
  - change in length of menstrual cycle
  - skipping menstrual periods
  - Risk of unintended pregnancy during perimenopause
  - Symptoms most commonly associated with hormonal status (estrogen deficiency-related menopause symptoms):
- Vasomotor symptoms: hot flashes, day sweats, night sweats
- Vaginal dryness/dyspareunia
- Other symptoms reported by midlife women that may or may not be associated with menopause:
  - Stiffness/soreness
  - Forgetfulness
  - Insomnia/sleep disturbances
  - Palpitations
  - Urine leakage
  - Urinary tract infections (UTIs)
  - Changes in libido
  - Fatigue
  - Mood swings, irritability, anxiety, depression
  - Headaches and backaches
- Not associated with perimenopause/menopause:
  - Major depressive disorder

Checklist Of Topics To Cover In Counseling:

Note: These topics will be addressed in greater detail in the following section on Managing Menopause.

Clinicians should be prepared to discuss the following topics related to managing common symptoms or reducing the risk of future health conditions. Some of these treatment options are likely to be raised by patients, and clinicians must be familiar with them even if they would not recommend them. Since the strength of the scientific research that demonstrates the efficacy of these treatments varies considerably, clinicians should be able to point out where the scientific evidence is strong and where it is weak or lacking. Information on the potential benefits and risks of all medications should be given. The following list of topics is not intended to recommend any specific treatments.*

Hot Flashes/Day Sweats/Night Sweats
Non-pharmacologic
· Dress in layers
· Identify and avoid triggers (e.g., hot rooms)
· Exercise (aerobically)
Pharmacologic
· ERT/HRT
· Clonidine
· Bellergal
· Low dose oral contraceptives (20 mcg estrogen)
· Herbal preparations/dietary supplements (see page 30)

Vaginal Dryness/Dyspareunia
Non-pharmacologic
· Vaginal lubricants/moisturizers
· Regular sexual stimulation
Pharmacologic
· ERT/HRT
· Vaginal estrogen creams
· Vaginal estrogen ring
· Low dose oral contraceptives
· Herbal preparations/dietary supplements (see page 30)

Possible Interventions for Preventing/Treating Diseases of Advancing Age
Coronary Heart Disease (CHD)
· Assessment of and counseling on risk factors
· Smoking cessation
· Exercise
· Healthful diet
· Weight loss (lower body mass index) if overweight
· Stress management
· Control of blood pressure if elevated

· Control of diabetes if present
· Optimal total serum cholesterol, LDL, HDL, and triglycerides
· ERT/HRT
· Statins
· Antioxidants (e.g., vitamins C and E)
· Adequate folic acid
· Soy

Osteoporosis

· Assessment of and counseling on risk factors
· Dietary calcium and vitamin D
· Exercise
· Fall prevention
· Smoking cessation
· Limit alcohol
· Bone mineral density (BMD) testing for:
· all postmenopausal women who present with fractures
· Consider BMD testing for:
· postmenopausal women under 65 who have one or more additional risk factors for osteoporosis (besides being Caucasian)
· all women 65 and older regardless of additional risk factors
· all women whose decision to begin treatment would be influenced by BMD result
· Consider osteoporosis treatment for all postmenopausal women who present with vertebral or hip fractures, or have a BMD T-score < -2 (or < -1.5 if they have additional risk factors)
- ERT/HRT
- Alendronate
- Risedronate
- Raloxifene
- Calcitonin
- Soy/phytoestrogens
- Calcium and Vitamin D (supplemental-not sufficient by themselves)

Early evidence suggests that ERT/HRT may prove beneficial for the prevention and/or treatment of the following conditions, but more research is needed:

Alzheimer's Disease

Colon Cancer

Macular Degeneration

*This document focuses on the symptoms mentioned in the HEDIS Management of Menopause measure, (i.e., vasomotor symptoms and vaginal dryness), which are known to be estrogen-related.

Managing Menopause

Typical Perimenopause/Menopause Experience

All clinicians caring for women should understand the typical menopause experience. Menopause occurs with the final menstrual period, which is known with certainty only retrospectively. Women who have not had a spontaneous menstrual period for one year are classified as postmenopausal.1 Perimenopause includes the entire menopausal transition plus one year after the final menstrual period. (See Glossary for additional definitions.)

Age at Menopause

A number of studies in the U.S. have estimated age at menopause. The most recent estimates are from the population-based Massachusetts Women's Health Study. The investigators estimated that women begin the menopausal transition (the time when they first notice changes in their bleeding patterns or begin to experience hot flashes) at about 47 years and have their last menses at about age 51. Women begin the menopausal transition about four years prior to menopause, with a range of two to seven years. Women who smoke tend to experience menopause two years earlier than women who do not smoke, and women who are nulliparous tend to experience menopause earlier than those who are multiparous. By age 55, over 90% of women have experienced menopause.2

Although the Massachusetts Women's Health Study is the largest population-based study of the menopausal transition completed to date, a few factors may limit the generalizability of its results. The majority of women were Caucasian and between 45 and 55 years old at the beginning of the study. As a result, the estimates of age at menopause may be somewhat higher than if women were entered in the study at age 40. Results may not apply across ethnic and racial groups of women not included in the study. The Study of Women and Health in the Nation (SWAN), a multi-site study of the natural history of menopause, is in progress. This study will include representation of African American, Japanese American, Chinese American and Hispanic women as well as Caucasians. As the results of the SWAN study are published, there should be a greater understanding of the natural history of the menopausal transition among several ethnic/racial groups of women in the U.S.

Perimenopausal Changes in the Menstrual Cycle

Recent evidence about the menopausal transition and its endocrine correlates suggests that division of the menopausal transition into discrete stages may enhance our ability to understand its relationship to health outcomes. Based on a population-based study of women in midlife, three menopausal transition stages have been proposed: early, middle and late.1 During the early stages of the transition to menopause, women have regular periods but notice changes in the amount of menstrual flow (often lighter, but it may be heavier and involve flooding or spotting), the number of days of flow (often fewer days of menses, but there may also be more days of menses), or changes in the lengths of their cycles. During the middle transition stage, women's menstrual cycles are irregular (with variability of six days or more between consecutive cycles) but women do not notice skipping of periods. During the late transition stage, women notice

skipping of periods, meaning that the interval between their cycles is double or more the length of their usual menstrual cycle. Often their periods are two to three months or more apart.

Symptoms Experienced during the Menopausal Transition

The most prevalent group of menopausal symptoms are the vasomotor symptoms, which include hot flashes, day sweats, and night sweats. Estimates of the percentage of women that experience hot flashes range up to 80%.

Although a number of symptoms have been attributed to the menopause, the prevalence of symptoms other than vasomotor symptoms and vaginal dryness was found to be unrelated to menopause in Canadian women3 and in a Norway cohort.4 Healthy midlife women may experience somatic, neuromuscular, mood fluctuations and other symptoms that are not exclusive to menopausal transition.5,6,7,8 If these symptoms are distressing, they will need to be explored and addressed.

Insomnia is prevalent among midlife women, and seems to be partially related to vasomotor symptoms: women with hot flashes had twice the rate of insomnia as women without hot flashes.2 ERT/HRT appears to improve sleep quality (i.e., increased duration of REM sleep) and reduce the time it takes to fall asleep in menopausal women.9,10 It is important to note that there are many additional causes of insomnia, so attributing insomnia to menopause simply because of a woman's menopausal transition status is not advised.

Depression is a problem reported by menopausal women, but current evidence does not link estrogen levels during the menopausal transition to serious depression.11 While some menopausal women may experience mild and transient depressed mood, serious clinical depression is not caused by menopause. Among U.S. and Canadian women participating in population-based studies, an estimated 23 to 38 percent of women report depressed mood during the perimenopause. Results of the Massachusetts Women's Health Study indicate that the best predictor of depression during the menopausal transition is prior depression.11 Women with a history of depression, including postpartum depression and PMS, could be at higher risk for depression during the menopausal transition than women who have not been depressed earlier in life.12,13 In prospective studies, women reporting depressed mood before menopause, a longer transition to menopause, and more severe menopausal symptoms were more likely to experience depressed mood during the menopausal transition and postmenopause.5

Results of population-based studies support an association between stress exposure and depressed mood.2,14 Given the general association of stress with symptoms, a reasonable explanation for symptoms, particularly dysphoric mood symptoms, could be found in the stressful nature of some women's lives. Longitudinal studies have revealed that women exposed to more stressful events in their lives were those most likely to experience subsequent dysphoric mood and vasomotor symptoms.3,11,13,15,16,17 Women with the most negative attitudes toward menopause and aging reported the most perceived stress and most severe vasomotor and dysphoric mood symptoms during subsequent years of follow-up.12,13,18,19

Longitudinal studies of midlife women demonstrated that those with diagnosed chronic illnesses were also at increased risk of depression.2,3 In another study, midlife women with chronic conditions who rated their health as fair or poor had more perceived stress and dysphoric mood.13

There is no evidence to support a "menopausal syndrome" in population-based studies, suggesting that such observations are largely confined to women seeking care in menopause clinics or consulting clinicians for distressing symptoms. Nonetheless, for some women the menopausal transition may precipitate severe distress. Studies of women attending menopause clinics reveal a high frequency of symptom-related visits. In a California study, 79% of visits by perimenopausal women were for physical symptoms such as vasomotor symptoms and 63% were for depression.20 Women most distressed by menopausal symptoms recalled having premenstrual symptoms prior to perimenopause.4,16,21 This finding suggests that there may be women who are more vulnerable to symptom distress during the transition to menopause.

There is some evidence that menopausal symptoms are a culture-bound phenomenon, with women from cultures not influenced by Western medicine reporting few symptoms or different symptoms.5 A study involving Japanese women revealed that their most frequently reported symptom was shoulder pain, not hot flashes.17 However, it is also possible that the infrequent reporting of hot flashes by Japanese women may be attributable to the high phytoestrogen content in their diets.

Unintended Pregnancy

Although the pregnancy rate in women 40 years and older is low, approximately 51% of pregnancies in this age group are unintended.22 Women in the perimenopausal stage are potentially able to conceive. Low dose oral contraceptives can provide protection against pregnancy as well as relief from estrogen-related menopausal symptoms.

Strategies for Managing Symptoms

Note: See the following section on Potential Risks of Pharmacologic Agents

Hot Flashes

Hot flashes are the most common symptom of menopause; the majority of menopausal women will experience them to some degree. Regular aerobic exercise can help decrease hot flashes. Other suggestions for menopausal women troubled by hot flashes are to dress in layers, and to try to pinpoint what triggers the hot flash (e.g., hot drinks, spicy food, alcohol, stress, hot weather, or a warm room) and avoid or modify the trigger, if possible.23

Estrogen replacement therapy (ERT) and hormone replacement therapy (HRT) have clearly been shown to be an effective treatment for hot flashes. Taking ERT/HRT on a short-term basis (1-5 years) may be a good strategy for women whose primary concern is hot flashes. Women will need to revisit the issue with their clinicians when it is time to decide whether to taper off ERT/HRT or consider continuing with it for longer-term prevention goals.

Clonidine, bellergal, and low dose oral contraceptives (20 mcg estrogen) have been shown to reduce the incidence of hot flashes. Oral contraceptives have the added benefit of regulating menses and preventing unintended pregnancy in perimenopausal women. Several clinical trials have demonstrated a mild but significant improvement in hot flashes with dietary phytoestrogen supplementation (e.g., soy products), and there is some (inconclusive) evidence that the herb black cohosh may reduce hot flashes and improve mood.24

Vaginal Dryness/Dyspareunia

The loss of estrogen associated with menopause causes changes in the vagina, which are more commonly seen in postmenopausal than in perimenopausal women. The vaginal lining may become thin and dry, which can cause painful intercourse as well as making the vagina more prone to infection. Vaginal lubricants/moisturizers can make intercourse more comfortable and regular sex may help the vagina maintain its elasticity. ERT/HRT, vaginal estrogen creams, vaginal estrogen rings, and low-dose oral contraceptives have been shown to help moisten the vagina and decrease dyspareunia, as well as decrease the incidence of UTIs.25 Consumption of soy products may also be helpful for vaginal dryness, but there are insufficient data to draw a firm conclusion.

Strategies for Preventing Diseases of Advancing Age

Strategies for preventing the diseases associated with advancing age can be multi-faceted, and include dietary, exercise, and possibly lifestyle changes as well as pharmacologic interventions. Counseling should consider the broad range of pharmacologic and non-pharmacologic interventions that can address the health considerations under discussion at the time of menopause. Counseling should also include the strength of the supporting scientific evidence for each of the interventions.

Most pharmacologic approaches to managing menopause carry risks as well as benefits. A clinician must have a thorough understanding of a patient's own and her family's histories of cancers, heart and cardiovascular disease, osteoporosis, and other conditions that may influence her inherent risk of developing disease or the degree to which a pharmacologic intervention might increase (or decrease) her risk.26

Coronary Heart Disease

Coronary heart disease (CHD) is the leading cause of death and a significant cause of morbidity in American women. The risk of CHD increases in older women. Although many women fear breast cancer more than heart disease, one in two women will eventually die of heart disease or stroke, while only one in 25 will die from breast cancer.27

Risk Factors for CHD(28)

- Positive family history of premature CHD (definite MI or sudden death before age 55 in a first-degree male relative, or before age 65 in a first-degree female relative)
- Hypertension
- Diabetes mellitus
- Current cigarette smoking
- Age and gender (women (55, or premature menopause and not on HRT)
- HDL<35 mg/dL
- LDL>160 mg/dL, if patient does not have CHD and has no more than one other CHD risk factor
- LDL>130 mg/dL if patient does not have CHD but has two or more other CHD risk factors or has other non-cardiac vascular disease
- Peripheral atherosclerosis or carotid artery disease (places patient in highest risk category)

Notes: High risk = 2 or more non-cholesterol risk factors.
HDL (60 mg/dL counts as a negative risk factor
HDL < 35 mg/dL is an independent risk factor for CHD

Possible Interventions for Prevention and/or Treatment of CHD

Women should:

- Incorporate regular physical activity into their daily routines.29
- Achieve and maintain desirable weight and body mass index (BMI). (BMI equals weight in kilograms divided by height in meters, squared. A BMI of 25-29.9 is considered overweight; a BMI of 30 or more is considered obese.)
- Learn stress management techniques.
- Eat a healthful diet, i.e., one low in fat, cholesterol, and salt, and high in dietary fiber. Depending upon cholesterol levels and risk factors for CHD, the American Heart Association's Step I or Step II diets may be indicated.30
- Consume adequate amounts of vitamins C and E (antioxidants that may help reduce the deposition of LDL in the arteries).

- Achieve and maintain a blood pressure <140/90 mm Hg (optimal = <120/<80)
- Normalize lipid levels based on risk factors:
  - total serum cholesterol < 200 mg/dL
  - LDL < 130 mg/dL (or < 160 mg/dL, depending on other risk factors)
  - HDL (35 mg/dL
  - triglycerides < 160 mg/dL

Note: People with existing CHD, peripheral cardiovascular disease, or diabetes should achieve an LDL(100 mg/dL. Secondary prevention will likely consist of a combination of the American Heart Association's Step II diet, lifestyle/risk factor counseling, exercise, and drug therapy. Adequate folic acid consumption may be beneficial, as it reduces the risk of elevated homocystine level, a cardiovascular risk factor.31

Prescription Medications

ERT/HRT

Epidemiological studies consistently find that women using ERT/HRT have a 40-50% lower risk of dying of coronary heart disease than women who do not take ERT/HRT. The apparent benefit is largely limited to current or recent use. A prospective randomized clinical trial of a particular type of HRT use in a group of women with severe existing CHD showed an increased risk of a CHD event in the first year of use, but an overall decrease over time.32 A number of observational studies have reported reduced mortality in women with existing CHD taking ERT/HRT. More research is needed.

ERT/HRT has been shown to decrease total cholesterol and LDL and also increase HDL. However, ERT/HRT can increase triglyceride levels. (Approximately 25-30 percent of the positive effect of ERT/HRT on CHD is related to lipid effects; the remainder may be related to direct vasodilatation, anti-oxidant effects, and improvement of insulin resistance.)24

Selective Estrogen Receptor Modulators (SERMS)

Raloxifene, a SERM, has been shown to lower serum concentrations of total and LDL cholesterol but does not increase total HDL. (A protective effect on atherosclerosis was reported in rabbits but not in monkeys. There is currently no available evidence of raloxifene's effect on CHD morbidity and mortality in humans.)

Statins

Statins (e.g., pravachol, simvastatin, and atorvastatin) are effective for treating hypercholesterolemia and lowering cardiovascular risk.
Nonprescription

Soy

A meta-analysis of 38 controlled clinical trials reported a variable but significant decrease in total cholesterol, LDL cholesterol, and triglycerides following a high dietary intake of soy protein. Soy protein intake averaged 47 grams/day among the studies. The subjects had fairly low initial serum cholesterol levels (average = 185 mg/dL), and the decreases in serum cholesterol and LDL cholesterol concentrations were strongly linked to subjects' initial levels. Soy estrogens may be responsible for most of the hypocholesterolemic effects of soy protein.33

More research is needed to determine optimum intake, but it seems safe for clinicians to encourage interested patients to consider including some soy protein in their diets.

Osteoporosis

Osteoporosis, the most common human bone disease, is characterized by low bone mass and microarchitectural deterioration of bone tissue, leading to bone fragility and an increased risk of fracture. An estimated 10 million Americans have osteoporosis, and another 18 million more have abnormally low bone mass, putting them at risk for painful and debilitating fractures. Postmenopausal Caucasian women are at highest risk, although osteoporosis also affects non-Caucasian women and men. Known risk factors only account for approximately 30% of the incidence of osteoporosis.

Risk Factors for Osteoporosis (34)

Nonmodifiable Risk Factors:

- Personal history of fracture as an adult*
- History of fracture in first-degree relative*
- Caucasian race
- Advanced age
- Female sex
- Dementia
- Poor health/frailty

Potentially Modifiable Risk Factors:

- ·Current cigarette smoking*
- Low body weight (<127 lbs. for average height*
- Estrogen deficiency from:
  - Menopause (spontaneous or surgical)
  - Early menopause (<age 45)
  - Prolonged premenopausal amenorrhea (>1 year)
  - Low calcium intake (lifelong)
  - Excessive alcohol intake
- Impaired eyesight
- Recurrent falls

- Inadequate physical activity
- Poor health/frailty

*Demonstrated in a large, ongoing prospective U.S. study to be key factors in determining risk of hip fracture (independent of bone density)

Possible Interventions for Prevention and/or Treatment of Osteoporosis

Women should:

- Be counseled on risk factors for osteoporosis.
- Obtain an adequate intake of dietary calcium (at least 1,200-1,500 mg per day). (Note: The National Institutes of Health believe that daily intake approaching or exceeding 2,000 mg is more likely to cause adverse effects than lower intakes.)
- Obtain an adequate intake of vitamin D (400 to 800 IU per day). Most women will get their recommended daily allowance through diet and exposure to sunlight; others can use supplements.
- Do regular weight-bearing and muscle-strengthening exercise. These exercises improve bone health, strengthen muscles, and improve balance (which will help prevent falls).
- Be counseled on fall prevention (e.g., taping down rugs, using night lights, etc.).
- Stop smoking.
- Keep alcohol intake moderate (i.e., a maximum of one drink per day, which equals 12 oz. beer, 5 oz. wine, or 1.5 oz. liquor.)
- Be evaluated for osteoporosis with bone mineral density (BMD) testing if:
  - they are postmenopausal and present with fractures.
- Consider BMD testing if:
  - they are postmenopausal, under 65, and have one or more additional risk factors for osteoporosis (besides being Caucasian);
  - they are 65 or older, regardless of additional risk factors; or
  - their decision to begin taking ERT/HRT or other treatment would be influenced by the BMD result.
- Be considered candidates for osteoporosis treatment if they present with vertebral or hip fractures or their BMD T-scores are below -2 in the absence of risk factors, or below -1.5 if other risk factors are present.

Prescription medications

ERT/HRT

ERT/HRT is effective for the prevention and treatment of postmenopausal osteoporosis for the duration during which it is used. It prevents bone loss in women in the early and late postmenopause. Epidemiologic studies of ERT/HRT indicate a 50-80% decrease in vertebral fractures and a 25% decrease in nonvertebral fractures with five years or more of use, and an anticipated 50-75% decrease in all fractures with 10 or more years of use. Based on

effectiveness and other potential benefits, it provides the greatest benefit relative to cost (although potential risks and patient preferences must be taken into account).

Alendronate

This bisphosphonate has been approved for prevention and treatment of osteoporosis. It inhibits bone loss in postmenopausal women, and increases BMD and decreases the risk of fracture in patients with osteoporosis. Well-conducted, controlled clinical trials indicate that alendronate reduces the risk of fracture at the spine, hip, and wrist by 50% in patients with osteoporosis.

Raloxifene

Raloxifene, a SERM, has been approved for the prevention and treatment of osteoporosis. It inhibits bone loss, and preliminary data in women with osteoporosis show that it reduces the risk of vertebral fracture by about 40-50%. It is less effective than ERT/HRT, alendronate, or risedronate.

Calcitonin

Salmon calcitonin, a hormone that inhibits bone resorption, is delivered as a single daily intranasal spray. It is recommended for women greater than five years postmenopausal with low bone mass relative to healthy premenopausal women. Efficacy data for calcitonin are currently weaker than for ERT/HRT, alendronate, or risedronate. (Results from a single controlled clinical trial indicated that it may decrease vertebral fractures by about 40%.)

Risedronate

This bisphosphonate is reported to be as effective as alendronate and did not cause more esophageal irritation than placebo in a randomized clinical trial. (FDA approval is anticipated in 2000.)

Nonprescription

· Soy/Phytoestrogens

Randomized clinical trials using a potent synthetic phytoestrogen derivative (ipriflavone) demonstrated a positive effect on bone density, although doses were much higher than achievable through dietary phytoestrogen intake (ipriflavone is not available in the U.S.). There is no data on fracture reduction. More research is needed.24

Possible Interventions for Prevention and/or Treatment of Other Diseases

Colorectal Cancer

According to the National Cancer Institute, fecal occult blood testing either annually or biannually in people age 50-80 decreases mortality from colorectal cancer. Regular screening by sigmoidoscopy in people over the age of 50 decreases mortality from colorectal cancer, but there is insufficient evidence to determine the optimal interval for such screening. Dietary excesses of

fat and calories may increase the risk, while adequate fiber, calcium and other micronutrients may decrease the risk of colon cancer. Vitamin D, in combination with calcium, may have a protective effect.35,36 Smoking and sedentary lifestyle are thought to increase risk for colorectal cancer.

Studies have been consistent in showing a 20-50% reduction in colorectal cancer in current and recent ERT/HRT users. Further study is needed.

Stroke

Following the guidelines above for prevention of CHD will also decrease a woman's risk of stroke. Evidence is inconsistent on the preventive effect of ERT/HRT on stroke.

Alzheimer's Disease

There is some evidence that ERT/HRT may be protective against cognitive decline and the incidence of Alzheimer's disease, but further study is required. It does not seem appropriate at this time to use ERT/HRT solely for the prevention or treatment of dementia and cognitive decline.

Age-Related Macular Degeneration

Some scientists have suggested an association between age-related macular degeneration (AMD) and high saturated fat, low carotenoid pigments, and other substances in the diet. There is evidence that the consumption of fresh fruits and dark leafy vegetables may delay onset or reduce the severity of AMD, and antioxidants (e.g., vitamins C and E) may also help. Exposure to sunlight, smoking, and hypertension may worsen AMD.37

A large case-controlled study suggested that ERT/HRT may significantly reduce the risk of developing AMD, with current users of ERT/HRT having half the risk of former users and nearly three-quarters less risk than never-users.38

Readers should be aware that a number of professional associations and health agencies have issued consensus statements on the management of menopause, and may wish to consult these statements to supplement the information in this section. These include: The American College of Obstetricians and Gynecologists, the American College of Physicians, the American College of Preventive Medicine, the American Geriatrics Society, The North American Menopause Society, the Society of Obstetricians and Gynaecologists of Canada, and the U.S. Preventive Services Task Force. (All of the preceding are listed in the Bibliography.)

POTENTIAL RISKS OF PHARMACOLOGIC AGENTS

ERT/HRT

Breast Cancer

There has been much controversy surrounding the relationship between ERT/HRT use and breast cancer. Some studies have shown an increased risk of breast cancer for women taking ERT/HRT and some have not. In studies that have shown an elevated risk, risk increased with longer duration of use. In one of these studies, the increased risk was estimated to be six cases per 1,000 women after 10 years of continuous use.39 This duration effect generally appeared after five years of use, was reduced after cessation of use, and had largely, if not wholly, disappeared about 5 years after discontinuation of ERT/HRT.39, 40

Compared to tumors in never-users, those in ever-users were less likely to have spread to axillary lymph nodes or to more distant sites and more likely to be localized in the breast. There was an increase in the relative risk of spread disease with increased duration of ERT/HRT use.39 Studies of mortality from breast cancer have shown lower mortality for tumors that developed while women were taking estrogen.41

Progestogens do not seem to diminish the risk associated with estrogen use and a recent study has suggested that they may increase breast cancer risk.42

As noted above, some studies have not found an increase in breast cancer risk with ERT/HRT use.43, 44, 45, 46 More research is needed on the relationship between ERT/HRT and breast cancer, and it is hoped that the National Institute of Health's Women's Health Initiative, when completed and analyzed, may provide an answer. Until then, women and their clinicians will need to make the best possible decisions using the existing data. Breast cancer is perhaps the most common fear of women considering ERT/HRT. In order for each woman to make the decision about therapy that is right for her, she and her clinician need to be fully informed on the current state of knowledge on this subject, as well as other risks and benefits of treatment.

Endometrial Cancer

Unopposed estrogen therapy (ERT) is associated with a two-fold to three-fold increase in the risk of endometrial cancer in women with an intact uterus.47 Clinical and epidemiological data suggest that the risk of endometrial cancer is not increased in women taking estrogen plus at least twelve days of progestogen per month.

Deep Vein Thrombosis

In the first year of treatment only, ERT/HRT slightly increases a woman's risk of deep vein thrombosis. Excess cases of DVT were 1/5,000 women and approximately 1/4,350 women in two separate studies.48, 49 Excess cases of pulmonary embolism were 1/20,000 women in another study.50

Gallbladder Disease

ERT/HRT slightly increases a woman's risk of gallbladder disease. In the Nurses Health Study, the relative risk ratio was 1.5-2.0.

Triglyceride Level

ERT/HRT (oral, not transdermal or vaginal) can raise triglycerides, a problem in women with significantly elevated triglyceride levels.

Short-term Side Effects

Bloating, headache, and breast tenderness occur in five to ten percent of women taking ERT/HRT. ERT/HRT may occasionally cause irritability or depressive symptoms, but for most women, it decreases these symptoms. Breast tenderness often improves after a few months. Most symptoms are mild and do not require discontinuation of therapy; they may improve with dose reduction. For example, breast tenderness can be minimized by temporarily using a lower dose of estrogen. (This strategy is particularly useful in women who are more than five years postmenopausal, as they may be more sensitive to replacement estrogen at first.) Unpredictable uterine bleeding occurs in the majority of women on continuous combined HRT during the first 6 to 8 months. Subsequently, bleeding is generally light and stops permanently in most women with endometrial atrophy. Women on cyclical HRT will experience regular, predictable bleeding that may stop after several years or continue.

Note: FDA labeling lists the following as contraindications to the use of both ERT/HRT and birth control pills:

- Known or suspected pregnancy
- Known or suspected breast cancer
- Estrogen-dependent neoplasia
- Undiagnosed abnormal vaginal bleeding
- Active thrombophlebitis or thromboembolic disorders

Alendronate

Upper Gastrointestinal Disturbance

Some women taking alendronate experience esophageal symptoms (chest pain, heartburn, painful or difficult swallowing). Bisphosphonates must be taken on an empty stomach, and the person must remain upright and refrain from eating or drinking for 30 minutes after taking the dose. A rare complication is esophageal ulceration, at times with hemorrhage. 51

Risedronate

In a randomized clinical trial, risedronate caused no more upper gastrointestinal symptoms than placebo. 52

Raloxifene

Deep Vein Thrombosis
Raloxifene produces a small increase in the risk of deep vein thrombosis. 53
Hot Flashes
Raloxifene increases hot flashes in a small percentage of women.

Low-Dose Oral Contraceptives

Serious risks, which are rare, include thrombophlebitis, pulmonary embolus, coronary thrombosis, retinal thrombosis, and stroke.

Statins

Liver Damage
Rare side effects are impaired liver function (which is usually reversible) and rabdomyolosis with acute renal failure secondary to myoglobinuria.
Calcitonin
No known risks except with previous allergy.

Clonidine

Frequent side effects include dry mouth, palpitations, drowsiness, dizziness, and hypotension.

Bellergal

The phenobarbital can be addicting, so bellergal should only be used for short periods of time.

Herbal Preparations and Dietary Supplements

Women who choose to use herbal and dietary supplements should know that they are not regulated by the FDA and frequently have not been rigorously tested in human subjects. There are generally no standards for dosage, so the amount of active ingredient may vary from brand to brand. Often, little is known about the efficacy or safety of these substances. For example, herbs or supplements with estrogen-like properties may reduce hot flashes, but it is possible that they may also increase a woman's risk of endometrial cancer.54

Black Cohosh

Black cohosh is a widely-used alternative to ERT/HRT to treat menopausal symptoms.24 Five small clinical trials in the German literature reported finding a significant improvement in hot flashes and mood with Remifemin (a brand name for black cohosh); it appeared superior to placebo and equivalent to 0.625 mg of conjugated equine estrogens for the relief of vasomotor symptoms.24 However, the numbers in each treatment group were small, most of the studies were uncontrolled, and there are no long-term follow-up data available. Possible side effects include nausea, vomiting, dizziness, visual disturbances, slow heartbeat, and excessive

sweating.55 Commission E, the German agency that regulates herbs, does not recommend using black cohosh for longer than six months.55

Soy/Phytoestrogens (24)

There is some evidence that soy may help decrease hot flashes and possibly vaginal dryness, but the number of trials has been limited and the results inconclusive. Although there are no standard recommendations about dose and formulation, the epidemiological evidence on phytoestrogens is derived from the typical Asian diet, which contains 20 to 150 mg of isoflavones or 20 to 50 grams of soy protein daily. It is not known if some of the benefits attributed to phytoestrogens are actually the result of their incorporation into the low-fat, high-fiber Asian diet. There is also no definitive evidence on the benefits (or risks) of phytoestrogen supplements. Additional research is needed.

Resources For Clinicians And Health Plan Quality Managers

Clinicians and health plan quality managers can periodically check the following journals and Web sites for new information on menopause management. The monographs, books, and other resources listed may also be helpful.

Journals

Obstetrics and Gynecology
Menopause: The Journal of The North American Menopause Society
American Journal of Obstetrics and Gynecology
Journal of Obstetric, Gynecological, and Neonatal Nursing
Journal of Women's Health
Fertility and Sterility
Journal of the Society of Obstetricians and Gynaecologists of Canada

Web Sites

American College of Obstetricians and Gynecologists (www.acog.org)
Association of Professors of Gynecology and Obstetrics (www.apgo.org)
The North American Menopause Society (www.menopause.org)
Society of Obstetricians and Gynaecologists of Canada (http://sogc.medical.org)
National Osteoporosis Foundation (www.nof.org)
Monographs/Professional Education Materials

Available from The North American Menopause Society
www.menopause.org
Menopause Management: Women's Health through Midlife and Beyond (CME available)
How to Develop a Menopause Discussion Group
CME programs addressing osteoporosis
Reprints of Society Consensus Opinions and Gallup Surveys

Available from the Association of Professors of Obstetrics and Gynecology
202-863-2507
www.apgo.org
Maximizing Menopausal Health: Opportunities for Intervention. (CME monograph)
Available from Duke University Medical Center
Fax: 919-681-7462
Therapeutic Options for Menopausal Health. (CME monograph)
Available from the American Association of Health Plans
www.aahp.org (select "Health Care Delivery" to access reports on women's health)
Advancing Women's Health: Health Plans' Innovative Programs in Osteoporosis

Available from the National Osteoporosis Foundation
Fax: 202-223-2237
www.nof.org
Physician's Guide to Prevention and Treatment of Osteoporosis

Books
Available from Academic Press
1-800-831-7799
www.apcatalog.com
Women and Health. M. Goldman and M. Hatch, editors. 1999. ISBN: 0122881451
Menopause. R. Lobo, J Kelsey, and R. Marcus, editors. 2000. ISBN: 0124537901
Available from Lippincott, Williams and Wilkins
1-800-777-2295
Treatment of the Postmenopausal Woman. R. Lobo, editor. 1999. ISBN: 0781715598

CD-ROM

Available from the New England Research Institute
617-923-7747
www.neri.org
Menopause and Hormone Replacement Therapy: Effective Patient Care (CME)
Decision-Making Aids/Tools

Developed by the Foundation for Informed Medical Decision-Making and available from Health Dialog, Inc.
1-888-289-7525
www.healthdialog.com
Treatment Choices for Hormone Replacement Therapy: A Shared Decision-Making Program (videotape)

Available from the Ottawa Health Decision Centre
613-798-5555
e-mail: ldrake@civich.ottawa.on.ca
Making Choices: Hormones after Menopause
A decision tool that consists of a practitioner's manual and an audiotape, booklet, and worksheet for women

Soon to be available from the Comprehensive Health Enhancement and Support System (CHESS)
206-616-9250
Menopause and Beyond: Getting Answers, Making Choices. This computer-based education and support program includes a decision tool and a system through which users can send questions to other women and experts and receive personal answers. CHESS is a joint development between the University of Wisconsin-Madison, Center for Health Systems Research and Analysis and the University of Washington Department of Family Medicine and School of Nursing.

Soon to be available from Group Health Cooperative of Puget Sound
206-287-2927
To Be or Not to Be on Hormone Replacement Therapy: A Workbook to Help You Explore Your Options. This decision tool is a 30-page booklet containing information and self assessments for menopause, HRT use, breast cancer, heart disease and fracture. It was developed specifically for use in managed care organizations or other primary care settings to prepare women to have a meaningful discussion about HRT with their clinicians.

GLOSSARY

Health Plan Employer Data and Information Set (HEDIS): HEDIS, a collaborative effort of purchasers, health plans, and consumer organizations under the auspices of the National Committee for Quality Assurance (NCQA), is the most widely used set of health plan performance measures. The measures, which are updated periodically, are designed to enable purchasers and consumers to assess and compare performance among health plans. NCQA also accredits managed care organizations and managed behavioral health care organizations that are able to meet national standards. NCQA's standards and performance measurements for accreditation fall into the following categories: access and service, qualified providers, staying healthy, getting better, and living with illness. HEDIS and accreditation guidelines are available from NCQA (1-800-839-6487; www.ncqa.org).

Menopause*: Natural menopause is the permanent cessation of menstruation resulting from the loss of ovarian follicular activity. Natural menopause is recognized to have occurred after 12 consecutive months of amenorrhea for which there is no other obvious pathological or physiological cause. Menopause occurs with the final menstrual period, which is known with certainty only in retrospect a year or more after the event. An adequate biological marker for the event does not exist.

Perimenopause*: Includes the period immediately prior to the menopause (when the endocrinological, biological, and clinical features of approaching menopause commence) and the first year after menopause.

Climacteric*: The phase in the aging of women marking the transition from the reproductive phase to the non-reproductive state. This phase incorporates the perimenopause by extending for a longer variable period before and after the perimenopause.

Premenopause*: The whole of the reproductive period prior to the menopause.

Postmenopause*: Dates from the final menstrual period, regardless of whether the menopause was induced or spontaneous.

Induced menopause*: The cessation of menstruation which follows either surgical removal of both ovaries (with or without hysterectomy) or iatrogenic ablation of ovarian function (e.g., by chemotherapy or radiation).

Estrogen Replacement Therapy (ERT): The most commonly used oral dose in this country is 0.625 mg of conjugated equine estrogens daily. Other dosages are 1-2 mg of oral estradiol, 0.625-1.25 mg of oral estropipate, and 0.05-0.1 mg transdermal estradiol. ERT is generally prescribed for women who have had their uterus removed.

Hormone Replacement Therapy (HRT): Generally, HRT refers to a combination treatment: estrogen plus progestogen, with the progestogen taken at least 12 days per month. This combination is used in peri- and postmenopausal women who have a uterus, as the progestogen

provides protection against the increased risk of endometrial cancer from unopposed estrogen. (Women without a uterus do not need to take progestogen.)

*These definitions were developed by the Council of Affiliated Menopause Societies (CAMS), the international policy organ of the International Menopause Society (IMS), and were approved by the Board of the IMS in October 1999. Wherever possible, CAMS left intact the current accepted definitions in the medical literature; many of these definitions are based on the World Health Organization's.

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