TALKING ABOUT MENOPAUSE:
A GUIDE TO IMPROVING THE DIALOGUE BETWEEN YOU AND YOUR PATIENTS

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PREFACE

This monograph, *Talking About Menopause: A Guide to Improving the Dialogue Between You and Your Patients*, is a project of The Menopause Care Collaborative (MCC), an educational initiative sponsored by Pfizer Inc. In 2012 the MCC brought together a faculty of 16 leading experts in women’s health and menopause care including primary care practitioners (family physicians, internists and nurse practitioners) and specialists from the fields of endocrinology, obstetrics/gynecology and behavioral health.

The MCC was formed to:

- Identify barriers to effective dialogue between clinicians and patients about menopause;
- Recommend practical strategies, resources and tools to help clinicians initiate and maintain productive dialogues about menopause in their busy practices; and
- Encourage clinicians to view the menopause dialogue as an opportunity to enhance the health and well-being of women during the menopausal transition and beyond, while improving their patients’ satisfaction with their care.

To achieve these aims, the *Talking About Menopause* project was initiated based on a comprehensive literature review and one-on-one interviews and small group working sessions with MCC faculty members. This work culminated in a full-day MCC Faculty Summit Meeting convened in Dallas, Texas in January 2012 to achieve consensus regarding current perspectives on menopause management and practical guidance for clinicians. Proceedings of the MCC Summit are summarized in this document, and provide the basis for talking about menopause which can also be found on PersonalMenopauseAnswers.com/home, for healthcare professionals. Please visit PersonalMenopauseAnswers.com/home for downloadable resources, including patient handouts and useful external links.

Pfizer Inc. is grateful to the MCC Faculty for contributing their invaluable expertise and insight to this important project:

**CO-CHAIRS**

**Jeffrey P. Levine, MD, MPH**  
*Director, Women’s Health Programs*  
*Professor of Family Medicine*  
*UMDNJ-Robert Wood Johnson Medical School*  
*New Brunswick, NJ*

**JoAnn V. Pinkerton, MD**  
*Medical Director, Midlife Health Center*  
*Professor of Obstetrics & Gynecology*  
*University of Virginia Health Sciences Center*  
*Midlife Women’s Health Consultant, Yale Health*  
*New Haven, CT*
FACULTY

Ivy M. Alexander, PhD, APRN, ANP-BC, FAAN
Director, Adult-Gerontological, Family, and Women's Health Primary Care NP Specialty Professor, Yale School of Nursing
Midlife Women's Health Consultant, Yale Health
New Haven, CT

Daniel E. Diamond, MD
Clinical Assistant Professor, Department of Family Medicine
University of Washington School of Medicine
Bremerton, WA

Murray Freedman, MS, MD
Clinical Professor, Department of Obstetrics & Gynecology
Medical College of Georgia
Augusta, GA

Susan Hoffstetter, PhD
Co-director, Vulvar and Vaginal Disorders Specialty Center
Associate Professor, Department of Obstetrics, Gynecology & Women's Health, Division of Urogynecology
St. Louis University School of Medicine
St. Louis, MO

Risa Kagan, MD, FACOG, CCD, NCMP
Clinical Professor, Department of Obstetrics, Gynecology & Reproductive Sciences
University of California, San Francisco
East Bay Physicians Medical Group
Sutter East Bay Medical Foundation
Berkeley, CA

Sheryl A. Kingsberg, PhD
Chief, Division of Behavioral Medicine
University Hospitals Case Medical Center MacDonald Women's Hospital
Professor, Departments of Reproductive Biology and Psychiatry
Case Western Reserve University School of Medicine
Cleveland, OH

Wendy S. Klein, MD, FACP
Associate Professor Emeritus of Internal Medicine, Obstetrics & Gynecology
Virginia Commonwealth University School of Medicine
VCU Institute for Women's Health
Richmond, VA

Cheryl Lambing, MD, FAAFP
Director, Professional Education and Community Outreach
Director, Osteoporosis Center, Ventura County
Clinical Professor, Family Medicine
University of California, Los Angeles
Cleveland, OH

Anita Nelson, MD
Director, Women's Health Care Clinic, Harbor-UCLA Medical Center
Professor, Obstetrics & Gynecology
UCLA School of Medicine
Los Angeles, CA

Gloria Richard-Davis, MD, FACOG
Professor and Chair, Department of Obstetrics & Gynecology
Associate Director, Center of Women's Health Research
Meharry Medical College
Nashville, TN

Patricia Sulak, MD
Professor of Obstetrics & Gynecology, Texas A&M College of Medicine
Director, Scott & White Sex Education Program
Texas A&M-Scott & White Memorial Hospital
Temple, TX

Holly L. Thacker, MD, FACP, CCD, NCMP
Director, Center for Specialized Women's Health, Cleveland Clinic
Associate Professor of Surgery, Cleveland Clinic Lerner College of Medicine
Case Western Reserve University
Cleveland, OH

Michelle P. Warren, MD
Medical Director, Center for Menopause, Hormonal Disorders, and Women's Health
Professor of Medicine and Obstetrics & Gynecology
Columbia University Medical Center
New York, NY

Susan Wysocki, RN, WHNP-BC, FAANP
Principal, iWomenHealth
Washington, DC
INTRODUCTION

When asked, women consistently say that they want to know more about menopause and the physical changes and symptoms they may experience during their menopausal years. They also want to know about their treatment options and participate in choosing therapies to treat their symptoms, maintain health and improve quality of life during and after menopause. But many women also say they don’t talk about these issues with their providers. When they look for information on their own they are often confused by what they find and unsure about what sources of information to trust.

They’d prefer this information come from you.

As a provider caring for midlife women, you have an important role to play in counseling women about their health questions and concerns related to menopause. However, conversations about menopause often take a back seat to other health issues. For a variety of reasons, women don’t necessarily volunteer information about their menopause experience and clinicians don’t always ask.

With the help of leading experts in menopause and women’s health who are part of the Menopause Care Collaborative (MCC), Talking About Menopause has been developed to help to fill that gap. It suggests counseling strategies, informational resources and tools for educating midlife women about menopause in your day-to-day practice, and for establishing a partnership that helps women make well-informed decisions about health and lifestyle choices during the menopausal transition and beyond.
PART 1: STARTING THE CONVERSATION

WHY MENOPAUSE MATTERS

Today women live, on average, nearly a third of their lives after menopause (Figure 1),3,4 which makes lowering disease risk and pursuing ways to maintain good health of paramount importance to all women in the years leading up to and after the occurrence of the final menstrual period.5 As women complete their reproductive years, they are often singularly aware of the finiteness of their being and become much more motivated to make lifestyle changes that will improve the quality and quantity of their remaining years.

As such, the menopausal transition provides you with the ultimate “teachable moment.”

Menopause is an opportunity to both improve the quality of care for midlife women and improve their health outcomes. This is true about menopause-related symptoms but also with regard to other common menopause- and age-related conditions affecting women at midlife, such as osteoporosis, osteoarthritis, cardiovascular disease,6 metabolic syndrome, diabetes,7 urogenital conditions, cognition and mood disturbances, weight gain and sleep issues. It’s an important time to encourage menopausal women to focus on lowering disease risk and pursuing ways to maintain good health and quality of life for the many years ahead of them.6

More effective dialogue about menopause can also improve the satisfaction of both you and your patients with the encounter and build trust in your relationship.1 A study conducted at a large managed care organization found that women aged 45 to 55 experiencing menopause-related symptoms who received a structured intervention that included a self-assessment questionnaire, brief physician counseling and supporting educational materials reported greater satisfaction with length of visit and satisfaction with medical care received than women who did not.1
Unfortunately, confusion persists about which patients are appropriate candidates for which therapies. In addition, some subjects like vaginal atrophy and sexual dysfunction can be uncomfortable topics for both patients and their clinicians. In the absence of effective clinician/patient dialogue about menopause, women may seek information from other, less reliable sources.

Therefore, your role is more important and challenging than ever.

Most women are interested in relieving symptoms and in preventing future illness – and in particular, they want individualized treatment based on their personalized risk assessment. New strategies and tools are needed to facilitate the discussion about menopause to help you provide patients with the more personalized approach that they are seeking.

**CHALLENGES TO EFFECTIVE DIALOGUE**

Women consistently say they want more information from their healthcare providers about options for menopause symptom management and maintaining their health and quality of life.

However, many women are not talking to their healthcare providers about these issues.

According to a 2012 survey by The Endocrine Society:²

- 69% of women with menopausal symptoms say symptoms negatively affect their quality of life.
- More than 60% of these women say they have not talked with their provider about hormonal or non-hormonal treatment options for their symptoms.
- 50% have not talked with their provider about lifestyle changes that could relieve symptoms.

It seems the menopause dialogue, particularly with regard to treatment options, remains challenging – that is, when it takes place at all.⁸ (Table 1.) In part, this is because women and clinicians now have more concerns and more questions, not only about hormone therapies (HT) but about other therapies including bioidenticals and complementary and alternative medicine approaches. To provide effective counsel, clinicians need a good understanding of the data about all treatment options, and the ability to tailor the risk/benefit discussion to each individual patient.

**Table 1:**

Challenges to Effective Communication Between Physicians and Patients⁸

When asked to identify challenges to effective communication between physicians and patients about menopause, gynecologists and primary care physicians participating in a national probability survey ranked them as follows:

- Confusing messages from media, healthcare professionals and friends .................. 80%
- Controversies about hormone therapy ................................................................. 56%
- Complicated issues surrounding treatment options ............................................. 45%
- My time constraints ............................................................................................. 43%
- Lack of available information about alternative treatment options .................. 27%
- Patients are not open about what they know/don’t know about menopause ........ 23%
- Patients appear to be managing their menopause on their own ......................... 17%
- My lack of knowledge about alternative treatment options .............................. 17%
- Patients are embarrassed to ask questions ......................................................... 14%
Symptoms and Conditions That May Be Experienced During Menopause

Common menopause-related symptoms include:

- Hot flashes and night sweats
- Irregular menses
- Vaginal dryness

Other symptoms reported by middle aged women that may or may not be associated with menopause:

- Mood changes
- Cognition disturbances
- Sleep disturbances
- Weight gain
- Fatigue
- Palpitations
- Forgetfulness
- Stiffness/soreness/joint pain
- Headaches, migraines and backaches
- Irritability
- Recurrent urinary tract infections
- Urinary urgency and/or incontinence
- Anxiety
- Depression not responsive to antidepressants
- Loss of libido

Figure 2:

Start the Conversation Early

Women can benefit from anticipatory guidance about the hormonal changes that occur with menopause and the symptoms they might experience, as well as knowing that treatment options are available. In addition, preventive healthcare recommendations and lifestyle modifications—diet, nutrition, exercise, smoking cessation, avoidance of excessive alcohol—may take on added relevance if women understand the potential effects of hormonal changes on their risks for conditions like osteoporosis and cardiovascular disease. The goal is to create a “menopause friendly” atmosphere where women feel:

- They can be open about their concerns;
- Questions are welcome; and
- Credible information will be forthcoming.

Estrogen levels in a woman’s body decrease abruptly around the final menstrual period, or menopause, but there is also significant fluctuation in the years preceding and following menopause—meaning that changes due to estrogen depletion may span a longer period than one might anticipate. (Figure 2.)

Women consistently report they don’t feel prepared for the physical changes and varied symptoms they may experience during perimenopause and menopause. Women may start experiencing symptoms that are new to them and that can affect their quality of life during perimenopause, as estrogen levels decline. Many women experience menstrual irregularities including shorter, longer and/or heavier periods. In addition, many begin to notice the onset or increased intensity of vasomotor symptoms (hot flashes, night sweats) during perimenopause. In late perimenopause, symptoms of genital atrophy and problems in sexual function may occur.


Table 2:

<table>
<thead>
<tr>
<th>Symptoms and Conditions That May Be Experienced During Menopause</th>
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<tbody>
<tr>
<td>Common menopause-related symptoms include:</td>
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<tr>
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<td>• Depression not responsive to antidepressants</td>
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</tbody>
</table>
Consider opening the door to menopause dialogue and carving out time for menopause-related patient education and counseling by offering your patients in their mid-40s, which for most will be early in perimenopause a 15-minute well woman visit specifically focused on menopause and perimenopause. Alternatively, consider allotting time for these women during their annual physical to talk about menopause/perimenopause. This time can be used to:

- Provide education and anticipatory guidance;
- Reassure patients by normalizing symptoms that may be difficult to discuss (e.g., urogenital symptoms, sexual dysfunction);
- Conduct a health assessment with particular focus on menopause-related issues;
- Reinforce relevant preventive and lifestyle recommendations; and
- Open the door to future discussion if and when questions and concerns arise.

Key components to consider including in this visit and suggestions for starting the conversation are described in Table 3.

### Table 3: The 15-Minute Well-Woman Menopause-Focused Visit

#### Part 1: Explore Informational Needs, Questions and Concerns

<table>
<thead>
<tr>
<th>Approaches to Consider</th>
<th>Sample Conversation Starters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start a patient-centered conversation</td>
<td>• A lot of women at this stage of life begin to experience symptoms such as irregular or heavier periods, hot flashes, night sweats, difficulty sleeping and other issues.</td>
</tr>
<tr>
<td>Explore your patient’s level of knowledge and attitudes/beliefs about menopause</td>
<td>• Have you noticed any of these or other changes that make you think you might be in perimenopause?</td>
</tr>
<tr>
<td>Provide anticipatory guidance and education</td>
<td>• How do you feel about menopause?</td>
</tr>
<tr>
<td>Leave the door open to future questions, discussion</td>
<td>• Have you heard or read much about menopause?</td>
</tr>
<tr>
<td>Educate women who inquire about hormone testing that it is not necessary</td>
<td>• How do you get your information about menopause?</td>
</tr>
<tr>
<td>• Every woman is different and many women go through the menopausal transition with no symptoms at all.</td>
<td>• If you are not experiencing any symptoms now that’s great.</td>
</tr>
<tr>
<td>• On the other hand, many women at this stage of life start to experience symptoms you’ve probably heard of like hot flashes and night sweats. Sometimes these are really distressing, sometimes they’re not – it all depends on the individual.</td>
<td>• Please feel free to come back and talk with me if you develop symptoms that become bothersome, and we can talk about your options.</td>
</tr>
<tr>
<td>• A symptom that lots of women don’t associate with menopause but is caused by declining estrogen is vaginal dryness, which can cause pain with intercourse and lead to other problems like urinary leakage or recurrent UTIs.</td>
<td>• Hormone testing is not needed or useful in most cases. Hormone levels swing dramatically day-to-day and don’t correlate with symptoms.</td>
</tr>
<tr>
<td>• It is more useful to simply pay attention to what your body is telling you.</td>
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</table>

#### PART 2: Discuss Health Assessment and Preventive Care

<table>
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<tr>
<th>Points to Consider</th>
<th>Suggested Discussion Topics</th>
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<tbody>
<tr>
<td>Conduct a menopause-related health assessment with special attention to:</td>
<td>• Risk factors for metabolic syndrome, CHD, stroke, VTE, osteoporosis and breast cancer</td>
</tr>
<tr>
<td>• Bowel, urinary, sexual health</td>
<td>• Schedule comprehensive physical and pelvic exam if none on record within last 12 months</td>
</tr>
<tr>
<td>Discuss preventive healthcare</td>
<td>• Potential effects of menopause and aging on weight gain distribution, sleep</td>
</tr>
<tr>
<td></td>
<td>• Diet, exercise, smoking, alcohol consumption, calcium and vitamin D intake, immunizations, normal weight and sexual health</td>
</tr>
</tbody>
</table>
Points to Consider About Hormone Testing
Perimenopause/menopause is a clinical diagnosis. Hormone levels do not correlate with symptoms and, for most patients, hormone testing is of little clinical value. Because of the dramatic swings seen day-to-day in hormone levels, tests of hormone levels are not only worthless but also possibly misleading. Diagnosing a woman as menopausal before she truly is could put her at risk for pregnancy. Simply asking a woman if she has noticed any change in her periods or any hot flashes or night sweats is an appropriate, patient-centered way to begin the menopause evaluation.

MAXIMIZE TIME WITH FOLLOW-UP VISITS AND TOOLS

Patients often raise menopause-related questions or concerns during an office visit scheduled for other reasons. You can gain additional time for symptom assessment, patient education and counseling by addressing menopause-related issues over several visits, if needed.

- Focus on the woman’s most important, or bothersome menopause concerns first – not everything has to be done at once.
- Schedule follow-up visits to both monitor progress and address the issues next in line.
- Explore alternative models for delivering menopausal care and patient education, including group and shared visits or referral to women’s health specialists.

Consider using simple, time-saving tools to rapidly assess areas of concern and track progress – for example, by providing patients with a self-assessment questionnaire to complete and return on a follow-up visit. There are several standardized questionnaires available for rating the severity of menopause-related symptoms and their effect on a woman’s quality of life.

Three to consider are:
- Utian Quality of Life Scale (UQOL)
- Menopause Rating Scale (MRS)
- Menopause Symptom Assessor

All three questionnaires are brief and can be completed by patients and scored by a clinician. All are available online (see the Appendix, page 19, for website links), and the MRS is available in multiple languages. The Menopause Symptom Assessor also provides patients with basic menopause facts.

In addition, you can help to fill the menopause information gap by providing patients with educational materials and pointing them to credible, trustworthy sources of information on the Internet or in the community. See the Appendix, page 19, for a listing to copy and share with your patients, or download a copy at PersonalMenopauseAnswers.com/home. Encourage patients to bring any questions or concerns they uncover in their research to the follow-up visit.
PART 2: CONTINUING THE DIALOGUE

MENOPAUSE SYMPTOMS, RELATED CONDITIONS AND COUNSELING STRATEGIES

While most women are aware that menopause (at its most basic) signals the permanent cessation of menstruation and end of fertility, they are often unaware that these are not the only consequences. Reductions in female hormones following menopause (primarily estrogen), complicated by the natural course of aging, are linked to a variety of conditions including vasomotor symptoms, urogenital atrophy, osteoporosis and increased cardiovascular risk and can have numerous other health effects throughout a woman’s body. (Figure 3.)

If women better understand the many changes that take place during the menopausal transition it can help to put their menopause experience in perspective and support informed decision-making. In addition, preventive healthcare and lifestyle modification recommendations regarding diet, nutrition, exercise, smoking cessation, avoidance of excessive alcohol, and the like, can take on added relevance if women understand the potential effects of hormonal changes on their risks for conditions like osteoporosis and cardiovascular disease.
INDIVIDUALIZING CARE

All women experience menopause, but no two women experience menopause quite the same way. Not all women will experience bothersome physical symptoms. The vast majority, however, will experience physical symptoms that are often distressing and may affect one or more important aspects of their lives.

Beliefs and attitudes toward menopause can affect how these symptoms are experienced. There is a difference, for example, if a woman believes menopause signals advancing age and ill health, or perceives it as a normal, natural progression. In addition, the degree to which women experience menopause-related symptoms varies widely from woman to woman and among women of different ethnic groups, cultures, socioeconomic groups, and even in different climates.

Most women want individualized treatment based on their own personal experience, needs and risk assessment.

Strategies to consider include:

- Use simple, time-saving tools to rapidly assess individual areas of concern.
  - Provide patients with self-assessment questionnaires that contain space for patients to note their individual beliefs or preferences about communication and attitudes toward menopause and treatment.
  - Several standardized questionnaires are available specifically for rating the severity of menopause-related symptoms and their effect on a patient’s quality of life. Three to consider are described in the Appendix, page 19, with website links provided.

- Ask open-ended questions to explore individual attitudes, beliefs and treatment preferences.
  - How do you feel about menopause?
  - Have you heard or read much about menopause?
  - How do you get your information about menopause?
  - How do you feel about treating your menopausal symptoms?

- Discuss risks and benefits of various treatment options within the context of patient’s own medical history, risk profile, and comfort level.
  - This is what the data say about the risks and benefits of this therapy among women in general; this is what that same data mean for someone like you.

- Evidence shows that healthcare providers should also be sensitive to other factors including:
  - Socio-cultural and ethnic background that may affect her concerns and choices
  - Economic and insurance status
  - Work situation, job satisfaction and stress
  - Other life stressors, particularly with personal relationships
  - Social supports
  - Overall quality of life
  - Current use of nonprescription complementary and alternative medicine approaches

VASOMOTOR SYMPTOMS

Of the approximately 43 million women in the U.S. who are of menopausal age, 17 million experience vasomotor symptoms, 9 million of whom experience moderate-to-severe symptoms. The impact of vasomotor symptoms on women’s lives may be considerable and is often underestimated.

- Hot flashes and night sweats can interfere with family life, work and other daily activities as well as with sleep. Women may find the experience profoundly disruptive and embarrassing.

- According to a 2007 survey by the National Sleep Foundation, 22% of postmenopausal women say they have a difficult time sleeping due to hot flashes or night sweats.

- Sleep disruption may then cause fatigue, decreased cognitive function and symptoms of depression, all of which can interfere with family and work life as well as sexual function and partner relationships.

Women want to know what’s happening, what’s normal and what’s not. Many women say they aren’t comfortable talking about it with others (even if they might joke about it among their friends). And they are often hesitant to pursue the issue with their own healthcare providers out of concern their symptoms will be trivialized, or the perception the topic will be burdensome due to time pressures — all of which can lead to miscommunication.

If you can explain vasomotor symptoms in patient-friendly terms it may help the symptomatic woman understand her symptoms and make sense of treatment options that might include trigger avoidance, lifestyle modifications, and/or hormone replacement therapy. For example:

"Vasomotor symptoms are thought to occur when estrogen levels fall and affect the body’s temperature regulating mechanism, so that even minor temperature changes can trigger hot flashes and sweating."

Additional background on the pathophysiology of vasomotor symptoms is provided in Figure 4.
**Figure 4:**

Small elevations in core body temperature (Tc) act within a reduced thermoneutral zone to trigger hot flashes in symptomatic postmenopausal women.

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<th>ASYMPtOMATIC</th>
<th>SYMPTOMATIC</th>
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Vasomotor symptoms are believed to be caused by a disturbance of the temperature-regulating mechanism in the hypothalamus, triggered by declining brain levels of estrogen and related to changes in central nervous system (CNS) neurotransmitters. The prevailing theory is that core body temperature in humans is regulated between an upper threshold for sweating and a lower threshold for shivering. Between these thresholds is a neutral zone (the thermoneutral zone) in which core body temperature is maintained without shivering or sweating. In symptomatic menopausal women, fluctuating estrogen levels alter CNS levels of norepinephrine and serotonin, lowering the sweating threshold and narrowing the thermoneutral zone, leading to inappropriate flushing and sweating, oftentimes followed by shivering. This causes even minor temperature fluctuations to trigger hot flashes and sweating. Estrogen restores the wider thermoneutral zone.

**TALKING ABOUT TREATMENT OPTIONS**

The clinical goal for managing vasomotor symptoms is to tailor therapy to each woman’s needs and preferences, using the various lifestyle, non-hormonal and hormonal options as appropriate. To achieve this, it is important to:

- Conduct a patient-centered assessment.
  - Rely on your patient’s own report of severity and how symptoms impact her daily life (e.g., discomfort, sleep disturbance, functioning at home and/or work).
  - Consider using simple patient self-assessment tools to rapidly identify areas of concern. Three to consider are described in the Appendix, page 19, with website links provided.
- Explore each patient’s level of knowledge and attitudes/beliefs toward symptoms and treatment.
  - Probe for questions, concerns, or misinformation that should be addressed, and treatment preferences that should be reflected in the management plan.
- Understand the patient’s own treatment goals and expectations for symptom relief.

- Discuss all available treatment options and their risks and benefits.
  - Include lifestyle, complementary and alternative medicine therapies, and prescription medications.
  - Tailor the risk discussion to take into account her health status and health risks, and her goals and expectations of therapy.
- Be prepared to continue the conversation.
  - If you sense a woman would like more information before making treatment decisions, consider providing patients with informational brochures or handouts, question-and-answer sheets, and/or directing them to credible, evidence-based educational sources on the internet or in the community.
  - See the Appendix, page 19, for a listing to copy and share with your patients, or download a copy at PersonalMenopauseAnswers.com/home.
  - Invite patients to return for a follow-up visit to answer any questions they may have.

**LIFESTYLE MODIFICATIONS**

Women who report that their vasomotor symptoms are only mildly bothersome, with little impact on quality of life, can be counseled about lifestyle changes that may help mitigate symptom impact (although efficacy has not been determined in randomized controlled clinical trials for some of these options).

Lifestyle modifications to suggest include:

- Keep core body temperature as cool as possible. Dress in layers, use a fan, sleep in a cool room, and drink water with ice when a hot flash occurs.
- Refrain from smoking.
- Exercise regularly to increase fitness, maintain a healthy weight, and promote more restorative sleep. Several studies have found a higher BMI (>27 kg/m²), as well as peri- and postmenopausal increases in body fat, to be predictors of hot flash frequency.
- Practice relaxation techniques. Enhance relaxation with meditation, yoga, massage or a leisurely lukewarm bath.
- Avoid perceived personal hot flash triggers (e.g., hot drinks, caffeine, spicy foods, alcohol, emotional reactions). While the limited data available does not support an association, anecdotally, many women report these triggers.
Strategies for Discussing Benefit-Risk Data With Your Patients

Use real-life numbers rather than percentages; in other words, explain using absolute vs. relative risk. • Instead of telling a patient "there is a 2% chance of the effect," say that "2 of every 100 women experience the effect."
• Instead of telling a patient "there is a 50% increase in the chance of the effect," say that "instead of 2 out of every 100 women experiencing the effect, 4 out of every 100 women will experience the effect."

Make sure your patient understands the difference between absolute and relative risk, especially for rare events. • Saying something "doubles the risk" can be misleading if the baseline risk is very low. If some negative health event occurs in only 1 out of 2,000 people a year, something that doubles the number of events (a relative risk of 200%) will result in it occurring in 2 out of 2,000 patients – still a rare event and a small risk.

Be aware that the meanings of "high risk," "moderate risk," "low risk," etc. are not universal. • To avoid confusion, consider only using these terms after they’re clearly defined.

Realize that some women may fear certain outcomes more than others, even if the risks are the same for certain outcomes. • The risks of stroke and invasive breast cancer with certain medications might be similar. Although stroke is more disabling, some women may fear breast cancer more and give it greater weight in their treatment decision.
Complementary and alternative medicine (CAM) refers to a broad range of therapies, including certain dietary changes, nutritional and herbal supplements, homeopathy, acupuncture, reflexology, magnet therapy, hypnosis, and other approaches. Many women explore CAM for menopause-related symptoms. In particular, the use of black cohosh, multibotanical supplements and dietary soy has grown dramatically, perhaps in part due to fear of prescription hormones. This makes it important for you to be prepared to provide your patients with up-to-date, evidence-based information.

Your patients should know that few CAM remedies for menopause-related symptoms have been scientifically evaluated and, to the extent they have been studied, robust evidence for the efficacy of many therapies is lacking. In randomized controlled clinical trials, soy foods, isoflavone supplements, vitamin E, and omega-3 fatty acids have not consistently been shown to be better than placebo for treating hot flashes.49 A summary of the evidence based for various CAM approaches is outlined in Table 5.

On the other hand, a growing body of evidence suggests that mind and body practices such as yoga, tai chi, qi gong, and acupuncture may benefit women during menopause.49 A 2010 review of 21 papers assessed mind and body therapies for menopausal symptoms. The researchers found that yoga, tai chi, and meditation-based programs may be helpful in reducing common menopausal symptoms including the frequency and intensity of hot flashes, sleep and mood disturbances, stress, and muscle and joint pain.49

Another 2010 review assessed studies that examined the use of acupuncture for hot flashes related to natural or induced menopause. The studies that the researchers included in their review were limited to acupuncture studies performed using needles stimulated by hand or electrically. The researchers found that acupuncture may reduce the frequency and severity of hot flashes; they also concluded that the effect may occur regardless of where the acupuncture needle is placed on the body. However, some studies did not provide sufficient evidence to support the use of acupuncture for hot flashes due to their small size and poor quality. Further research is needed to provide more conclusive results.39

In general, providing information on CAM therapies will involve being prepared with available clinical evidence and being sensitive to your patients’ preferences, while taking into account your own clinical experience with such therapies. Counseling strategies to consider include:

- Respectfully obtain details of products/treatments being utilized.
- Provide the most up-to-date, best evidence available.
- Consider it a reasonable therapy if the patient is benefiting from it, if it is not harmful with respect to drug interactions or side effects, if it may have other beneficial effects in the body, and is not unduly expensive.

### Table 5: Evidence For Complementary and Alternative Medicine (CAM) Approaches For Menopause Symptom Management

<table>
<thead>
<tr>
<th>Botanical Remedies</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Black cohosh</strong> (Actaea racemosa, Cimicifuga racemosa)</td>
<td>Most-studied botanical, results have been mixed. A plant or part of a plant used for its flavor, scent, or potential therapeutic properties. Includes flowers, leaves, bark, fruit, seeds, stems, and roots. A study funded by the National Center for Complementary and Alternative Medicine and the National Institute on Aging found that black cohosh, whether used alone or with other botanicals, failed to relieve hot flashes and night sweats in postmenopausal women or those approaching menopause. Other research suggests that black cohosh does not act like estrogen, as once was thought.39 United States Pharmacopeia experts suggest <strong>women should discontinue use of black cohosh and consult a healthcare practitioner if they have a liver disorder or develop symptoms</strong> such as abdominal pain, dark urine, or jaundice. There have been several case reports of hepatitis, as well as liver failure, in women taking black cohosh. It is not known if black cohosh was causative. Although these cases are very rare and the evidence is not definitive, scientists are concerned about the possible effects of black cohosh on the liver.</td>
</tr>
<tr>
<td><strong>Dong quay</strong> (Angelica saneness)</td>
<td>Efficacy has not been demonstrated to be significantly different from placebo.39 Dong quay is known to interact with and increase the activity of warfare, potentially increasing the risk of bleeding complications.</td>
</tr>
<tr>
<td><strong>Ginseng</strong> (Panax ginseng or Panax quinquefolius)</td>
<td>Ginseng may help with some menopause-related symptoms, such as mood symptoms and sleep disturbances, and enhance overall sense of well-being; however, it has not been found helpful for hot flashes.39</td>
</tr>
<tr>
<td><strong>Kava</strong> (Piper methysticum)</td>
<td>Kava may decrease anxiety, but there is no evidence that it decreases hot flashes. It is important to note that kava has been associated with liver disease. The U.S. FDA has issued a warning to patients and providers about kava because of its potential hepatotoxicity.39</td>
</tr>
<tr>
<td><strong>Oil of Evening Primrose</strong></td>
<td>No significant decrease in hot flashes in one trial.42 May potentiate seizure side effects in some medications (e.g., phenothiazines).42</td>
</tr>
<tr>
<td><strong>Red clover</strong> (Trifolium pratense)</td>
<td>Controlled studies have found no consistent or conclusive evidence that red clover leaf extract reduces hot flashes. Clinical studies in women report few side effects, and no serious health problems have been discussed in the literature. However, there are some cautions. Some studies have raised concerns that red clover, which contains phytosterogens, might have harmful effects on hormone-sensitive tissue (for example, in the breast and uterus). (See box below for more information on phytosterogens.)39</td>
</tr>
</tbody>
</table>
Soy

The scientific literature includes both positive and negative results on soy extracts for hot flashes. When taken for short periods of time, soy extracts appear to have few if any serious side effects. However, long-term use of soy extracts has been associated with thickening of the lining of the uterus.\(^{18}\)

Other CAM Approaches

Acupuncture

Results have been mixed. Of eight studies published between 1995 and 2008, three documented a significant decrease in hot flash severity; none of the others did. A recent meta-analysis concluded that convincing evidence for the use of acupuncture for hot flashes was lacking.\(^ {43}\) However, placebo effects and relaxation achieved with this well-accepted complementary therapy may reduce hot flashes enough to be beneficial for some women.\(^ {42}\)

Yoga

Pilot trials show benefit.\(^ {40}\)

Homeopathy

Efficacy has not been demonstrated to be clinically significant compared with placebo.\(^ {40}\)

BIOIDENTICALS/COMPOUNDED BIOIDENTICALS

Women’s interest in bioidentical hormone therapy has increased in recent years. Some bioidentical hormone therapies (BHTs) are FDA-approved and chemically identical to those produced by the ovaries. Often, however, BHTs are custom-made formulations of one or several hormones compounded by a pharmacy for an individual according to a clinician’s prescription. Such products are not FDA-approved or rigorously tested, and may not be consistent in composition or potency from batch to batch. Further, some forms, e.g., transdermal progesterone, are not absorbed sufficiently. Use of non-FDA approved BHT formulations is growing exponentially.

When your patients ask you about compounded BHTs (or are already taking them), it is appropriate to provide objective information and for you to correct misperceptions.

According to the North American Menopause Society:\(^ {44}\)

Healthcare providers who prescribe “bioidentical hormones” often claim that these products are more safe and effective than clinically tested and government-approved hormones produced by large pharmaceutical companies. They also may assert that “bioidentical hormones” slow the aging process. There is no scientific evidence to support any of these claims.

Government-approved hormone products are required by law to tell you about possible risks and side effects in a package insert. Custom-compounded hormones are not required to provide this information, but this does not mean they are safer. They contain the same active hormones (such as estradiol and progesterone), so share the same risks.

It is also important to consider that:

- Non-FDA approved BHT formulations and dosing are often based on saliva hormone testing in the patient; these tests are inaccurate and unreliable.\(^ {45}\)
- Though promoted or perceived by women as “natural,” the benefits and risks of compounded BHTs are unknown compared to FDA-approved formulations.

If a patient feels strongly about BHTs, it’s appropriate to acknowledge her desires while discussing the unknown benefits and risks – and importantly, documenting this discussion in the medical record, as you would with regard to FDA-approved versions.

UROGENITAL ATROPHY

Adequate levels of circulating estrogen are required to maintain the normal structure and function of the urogenital tract.\(^ {12,46}\) Therefore, one of the most inevitable consequences of estrogen deficiency is urogenital atrophy.

- In observational studies, 27% to 55% of postmenopausal women report vaginal dryness and 19% report irritation or itching.\(^ {12}\)

- Dyspareunia (pain during intercourse or attempted intercourse) is often a presenting symptom of genital atrophy and may affect up to 75% of postmenopausal women.\(^ {47}\)

Despite this, just 20% to 25% of women who experience symptoms of urogenital atrophy will seek treatment despite the availability of effective treatment options.\(^ {48}\)

Women may not associate the effects of urogenital atrophy with menopause and may not mention them to their clinicians. As a result, these problems often go unrecognized and undertreated, despite their potential impact on sexual function and quality of life.\(^ {49}\) While other symptoms of menopause, like night sweats and hot flashes, will lessen over time, painful intercourse is unlikely to get better on its own and can become worse over time.

Strategies to consider for starting the conversation with your patient:

- **Invite a discussion, now or in the future**
  - “Talking point: Many women start to notice vaginal dryness or pain with intercourse as they approach menopause. Do you have any concerns about this that you would like to discuss?”

- **Normalize the experience**
  - “A common symptom that lots of women don’t associate with menopause but is caused by declining estrogen is vaginal dryness, which can cause pain with intercourse and lead to other problems such as recurrent UTIs.”

- **Reassure your patient that effective treatments are available**
  - It’s not necessary to “just live with it.”
Causes and Consequences of Urogenital Atrophy

With the loss of estrogen, the vaginal walls become thin, dry, inelastic and easily traumatized. The vagina shortens in length, and the introitus constricts. Symptoms vary widely from woman to woman and can include itching, burning, inadequate lubrication during sexual activity, and pain with penetration. Recurrent urinary tract infections (UTIs) are a potential urologic complication of estrogen insufficiency, and urologic symptoms may include increased urinary frequency, urgency and incontinence. As a consequence of estrogen deficiency, vaginal pH is no longer acidic, and there is loss of lactobacilli and corynebacterium. This change in the normally protective ecosystem of the vagina allows potentially pathogenic organisms to become part of the vaginal flora and predispose women to UTIs. 

Urogenital atrophy results in a cycle of intercourse-related discomfort and sexual avoidance. Diminished sexual activity compounds the atrophic process and is an example of the "use it or lose it" phenomenon. Sexual dysfunction is an important quality of life issue, especially for women in whom menopause is induced by chemotherapy or surgery. The marketing of erectile dysfunction medications to the male partners of menopausal women has further amplified this issue. Sexual activity is normal and desirable, irrespective of age. Women can be adversely affected by bothersome urogenital symptoms in their most basic activities of daily living.

While quite noticeable on visible inspection, women with vaginal atrophy often remain asymptomatic until they develop pain with intercourse, tears in fragile vaginal tissue and bleeding, vaginitis, painful urination or recurrent UTIs. Unfortunately, urogenital atrophy is often an unrecognized, underlying factor in recurrent UTIs, and women are subjected to repeated courses of antibiotics that don’t treat the underlying problem and have consequences for causing even more change to the vaginal flora.

TALKING ABOUT TREATMENT OPTIONS

Many women are unaware that corrective therapy for urogenital atrophy is available or that such issues may be treated. Your patients can be reassured that effective treatment options for certain aspects of urogenital atrophy are available. It is not necessary to “just live with it.”

Treatment of urogenital atrophy depends on the type and severity of symptoms.

- Over-the-counter (OTC) therapies such as nonhormonal moisturizers and lubricants can decrease friction during intercourse and relieve mild vaginal dryness. They can be purchased without a prescription, and are used prior to sex to offer temporary relief of vaginal dryness. They are designed to lessen symptoms rather than treat the root cause of the pain.

- Prescription HT restores tissue and is the most effective treatment for moderate-to-severe symptoms of urogenital atrophy, e.g., vaginal dryness, dyspareunia, and atrophic vaginitis. (See Figure 5.)

Many systemic HT products and local vaginal HT products are approved for urogenital atrophy. When only urogenital atrophy is to be treated, local vaginal ET has been shown to be more effective than systemic HT and is usually advised unless there are other reasons for systemic therapy, e.g., because of bothersome VMS symptoms or to prevent osteoporosis in a woman at risk. Because endometrial hyperplasia increases with greater dosing and duration of estrogen exposure, any uterine bleeding should be thoroughly evaluated. Adding a proestrogen with long-term use of systemic estrogen therapy may help reduce the risk of endometrial hyperplasia in a woman with a uterus.

Figure 5:

**Improvement in Vaginal Maturation with Local Vaginal Estrogen Therapy**

<table>
<thead>
<tr>
<th>Before Treatment</th>
<th>During Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Superficial cells</strong></td>
<td><strong>Superficial cells</strong></td>
</tr>
<tr>
<td><strong>Intermediate cells</strong></td>
<td><strong>Intermediate cells</strong></td>
</tr>
<tr>
<td><strong>Parabasal cells</strong></td>
<td><strong>Parabasal cells</strong></td>
</tr>
<tr>
<td><strong>Basal cells</strong></td>
<td><strong>Basal cells</strong></td>
</tr>
<tr>
<td><strong>Vaginal epithelium</strong></td>
<td><strong>Vaginal epithelium</strong></td>
</tr>
</tbody>
</table>

After menopause, cytologic changes in vaginal tissue associated with estrogen deficiency include an increase in parabasal and intermediate cells and a large decrease in superficial cells. By restoring estrogen during treatment, research has shown that local vaginal estrogen therapy rebuilds vaginal tissue, addressing the underlying cause of vaginal symptoms including vaginal dryness and painful intercourse due to menopause.
OSTEOPOROSIS AND FRACTURE

Osteoporosis increases the risk of fractures that can result in substantial morbidity/mortality in postmenopausal women.

- Hip fractures cause up to a 25% increase in mortality risk within one year.
- Approximately 25% of women require long-term care after a hip fracture, and 50% will have some long-term loss of mobility.53

Your patients may not be aware that they are at risk for or already have osteoporosis until a fracture occurs. The time in a patient’s life prior to menopause offers you a window of opportunity to begin talking with your patients about the risk of bone loss and fracture associated with menopause and aging. It is also a good time to reinforce the importance of preventive strategies like eating a balanced diet, obtaining adequate calcium and vitamin D, exercising, avoiding cigarette smoke and excess alcohol consumption— all things that have health benefits beyond osteoporosis prevention.

Systemic hormone therapy (HT) products are approved for osteoporosis prevention but not for treatment, with demonstrated beneficial effects on bone mass density and reducing fracture risk. When prescribing solely for the prevention of postmenopausal osteoporosis, HT should be considered only for women at significant risk of osteoporosis and non-estrogen medications also should be carefully considered. An exception is for women undergoing early menopause who require preventive therapy.56

In these cases, The North American Menopause Society suggests considering HT or oral contraceptives over bone-specific treatments, unless there is a contraindication, and reassessing when they reach the age of normal menopause. Generally, patients should be treated with the lowest effective dose; subsequent adjustments can be made based on the individual clinical and bone mineral density responses.54

Help your patients clearly understand their risk of fracture and the importance of therapy in osteoporosis prevention, and strive to identify and address any barriers to adherence the patient may have.

OTHER SYMPTOMS/CONDITIONS THAT MAY BE EXPERIENCED DURING MENOPAUSE

Menopausal women often present to their healthcare providers with significant symptoms that may or may not be directly associated with menopause.

The more common of these include:

- Mood changes or depression
- Sleep disturbances and/or insomnia
- Changes in cognitive function

MOOD CHANGES OR DEPRESSION

Most women make the transition into menopause without experiencing depression.3 However, symptoms of depressed mood, anxiety and stress along with a decreased sense of well being are common among women during menopause and sometimes are among the primary menopausal symptoms your patients may report to you.36 Mood changes have been observed in up to 23% of peri- and postmenopausal women.55

Common and distressing symptoms include sadness, irritability, tearfulness, insomnia, fatigue, decreased memory and concentration, and depression. Women who are especially vulnerable to symptoms of depression during menopause include:

- Women with a history of premenstrual syndrome, premenstrual or post-partum depression;
- Women who report significant stress, sexual dysfunction, physical inactivity or hot flashes;1 and
- Women who report low social support.55

The extent to which these symptoms are a direct impact of hormonal changes during menopause remains controversial. Women at midlife are subject to considerable stresses, many of which may trigger mood changes or depression.

Management strategies for you to consider include:

- Attempt to differentiate among mood changes commonly seen at menopause—e.g., irritability, mood swings, loss of control—often due to sleep disturbance/insomnia caused by night sweats or brought on by other life events—and those that may be signs of serious depression. These distinctions are further complicated when caring for women who may have menopausal problems superimposed on a pre-existing clinical depression or anxiety.
- Be prepared to conduct an initial assessment of psychological health, including screening for clinical depression and significant anxiety.
  - Validated screening tools, including the Patient Health Questionnaire (PHQ)-9, are available; see the Appendix, page 19, for a website link to the PHQ-9.
  - Consider referral to a mental health professional for further evaluation or start antidepressant therapy.
SLEEP DISTURBANCE/INSOMNIA

Menopausal women frequently report problems with sleep, ranging from inadequate and unrefreshing sleep to insomnia. Poor sleep is associated with muscle aches, mood changes (dysphoria), tension, irritability, difficulty concentrating and performing tasks.¹

According to a 2007 National Sleep Foundation survey:²
- About 46% of women aged 40-54 and 48% of women aged 55-64 reported sleep problems.
- Peri- and postmenopausal women sleep less, have more frequent insomnia symptoms, and are more than twice as likely to use prescription sleeping aids as premenopausal women.
- Sleep problems resulted in a greater number of days at work missed or arriving late.

COGNITIVE FUNCTION

Many women report difficulty concentrating, remembering things, thinking clearly and other cognitive issues around the time of the transition to postmenopause.³ ⁶²% of women (mean age 46.7 years) who were surveyed as part of the Seattle Midlife Women’s Health Study reported that some type of undesirable memory change had occurred within the last few years.⁴

Multiple factors are likely involved. Night sweats may disturb sleep, affecting the ability to concentrate or be productive at work or home. Normal cognitive aging or other midlife stressors may also contribute to these symptoms. Indeed, most women interviewed for the SMWHS did not attribute their memory changes primarily to changes in their menstrual cycle or to hormones, but more to stress, aging and their physical health.⁴

While there is some evidence that memory can be affected in the immediate aftermath of surgical menopause, there is no firm evidence that memory or other cognitive skills actually decline as a direct consequence of natural menopause.⁵⁻⁶

A woman presenting to her clinician with bothersome cognitive concerns may benefit from exploration of possible vasomotor symptoms, sleep dysfunction, depression, life stressors or other conditions that may benefit from therapeutic intervention. Worrisome memory issues, often confirmed by family members, may warrant referral for evaluation to rule out early dementia.
CONCLUSION

During the menopausal transition women experience a variety of significant physical changes that can impact their lives in a variety of ways. Many women are often unprepared for what they will experience. Clinicians should strive to “open the door” for women transitioning to menopause by helping them understand and anticipate what may occur. This is important not only to set the stage for productive clinician-patient dialogue if and when the woman experiences bothersome symptoms, but to encourage healthier lifestyles needed during the postmenopausal years.

Therapeutic options for managing menopause-related symptoms include lifestyle changes, complementary and alternative medicine approaches and hormone therapies.

Open, candid dialogue between clinician and patient is critical to successful management of menopause-related symptoms. It fosters an approach to management that includes patient-centered assessment of symptoms and their severity; individualized assessment of the patient’s health risk factors, priority treatment goals and preferences; and collaborative decisions between the patient and clinician about management approaches. Clinicians who participate in the dialogue about menopause with their patients can play an important role in educating, equipping and empowering women to make well-informed decisions about their own health and lifestyle choices, in ways that can help protect health and well-being during the menopausal transition and for many years to come.
APPENDIX:

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TALKING ABOUT MENOPAUSE: A RESOURCE GUIDE (PATIENT HANDOUT) 22
RESOURCES

FOR CLINICIANS

ASSESSMENT TOOLS

• Utian Quality of Life Scale (UQOL)\(^\text{13}\)
  A validated 2-page instrument that clinicians can use to gain important information from women about menopause-related quality of life. The self-completed Consumer Questionnaire on page 1 can be filled out by patients during office visits; then use the Scoring Summary on page 1 to tally patient replies. The Consumer Questionnaire page can be photocopied, as needed, but the Scoring summary page requires printing on a color copier.

• Menopause Rating Scale (MRS)\(^\text{14}\)
  A validated 1-page self-completed scale that can be filled out patients during or between office visits to assess menopausal symptoms and evaluate symptom severity over time. The scale is in widespread use and available in 25 languages.
  Available at: [http://www.menopause-rating-scale.info/languages.htm](http://www.menopause-rating-scale.info/languages.htm)

• Menopause Symptom Assessor\(^\text{15}\)
  A self-completed questionnaire designed to help your menopausal patients recognize and assess symptoms associated with menopause, and to help you understand the severity of their symptoms and their frequency.
  Available at: [http://pfizermenopause.com/pdfs/Menopause%20Symptom%20Assessor.pdf](http://pfizermenopause.com/pdfs/Menopause%20Symptom%20Assessor.pdf)

HORMONE THERAPY TOOLS

• The 2012 Hormone Therapy Position Statement of the North American Menopause Society\(^\text{16}\)

• Hormone Therapy Charts
  (Source: North American Menopause Society)
  NAMS has prepared these charts for healthcare providers to help clarify the wide variety of estrogen and progestogen products that are now available in the US and Canada. The charts include oral, vaginal, transdermal and topical estrogen therapy ET products, progestogens used for estrogen-progestogen therapy EPT, and combination estrogen-progestogen therapy products.
  Available at: [http://www.menopause.org/publications/clinical-practice-materials/hormone-therapy-charts](http://www.menopause.org/publications/clinical-practice-materials/hormone-therapy-charts)
RESOURCES

FOR PATIENTS

Numerous resources are available for you to provide patients that can help answer common questions and concerns about key topics while educating about menopause and options for symptom management.

PATIENT HANDOUTS

• **Talking About Menopause: A Resource Guide**
  This Guide provides patients with sources of credible, up-to-date online sources of information about menopause they may wish to explore. See page 19 of this Appendix for the Guide which may be copied to share with your patients, or download a copy at PersonalMenopauseAnswers.com/home.

SYMPTOM MANAGEMENT

• **Treating Hot Flashes: A MenoNote from NAMS**
  (Source: North American Menopause Society)
  Available at: www.menopause.org/docs/for-women/mnflashes.pdf

• **Vaginal Dryness: A MenoNote from NAMS**
  (Source: North American Menopause Society)
  Available at: www.menopause.org/docs/for-women/mndryness.pdf

• **Vaginal Atrophy**
  (Source: Hormone Health Network/The Endocrine Society)
  Available at: www.hormone.org/Resources/upload/FS_MWH_Vaginal_Atrophy_EN-6-12-2.pdf

HORMONE THERAPY

• **Hormone Therapy for Women in 2012**
  (Source: North American Menopause Society)
  Available at: www.menopause.org/docs/default-document-library/psht12patient.pdf?sfvrsn=2

COMPLEMENTARY AND ALTERNATIVE MEDICINE

• **Complementary and Alternative Medicine (CAM) for Menopausal Symptoms**
  (Source: Hormone Health Network/The Endocrine Society)
  Available at: www.hormone.org/Menopause/upload/FS_MWH_CAM_Menopausal_EN-web.pdf

BIOIDENTICAL HORMONES

• **Bioidentical Hormone Therapy – Custom-Compounded vs. Government-Approved: A MenoNote from NAMS**
  (Source: North American Menopause Society)
  Available at: http://www.menopause.org/docs/for-women/mnbiodenticals.pdf

• **Bioidentical Hormones and Menopause**
  (Source: Hormone Health Network/The Endocrine Society)
  Available at: http://www.hormone.org/Resources/upload/FS_MWH_Bioidentical_Hormones_EN-web.pdf
TALKING ABOUT MENOPAUSE

A RESOURCE GUIDE

Here are a number of online women’s health and menopause information resources you may want to take the time to explore.

Association and Community Websites

Healthy Women
http://www.healthywomen.org

The Hormone Foundation (A website run by The Endocrine Society, the world’s oldest, largest, and most active organization devoted to research on hormones and the clinical practice of endocrinology)
http://www.hormone.org

Our Bodies Ourselves
http://www.ourbodiesourselves.org

Medical Websites

American Congress of Obstetricians and Gynecologists
www.acog.org

American Society for Reproductive Medicine
www.asrm.org

American Urogynecologic Society
www.augs.org

Association of Physician Assistants in Obstetrics and Gynecology
www.paobgyn.org

MayoClinic.com Menopause Information (A website offering medical information from the physicians, scientists, and researchers of Mayo Clinic)
http://www.mayoclinic.com/health/menopause

North American Menopause Society
www.menopause.org

WebMD: Menopause Health Center (A health information site with medical news, features, reference material, and online community programs)
http://www.webmd.com/menopause

Government Websites

Medline Plus (Health information from the National Library of Medicine. Includes medical journal articles, information about drugs, and more)

National Center for Complementary and Alternative Medicine
http://nccam.nih.gov

National Women’s Health Info Center
http://www.womenshealth.gov

Office of Research on Women’s Health
http://orwh.od.nih.gov

Wise Woman
http://www.cdc.gov/wisewoman
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