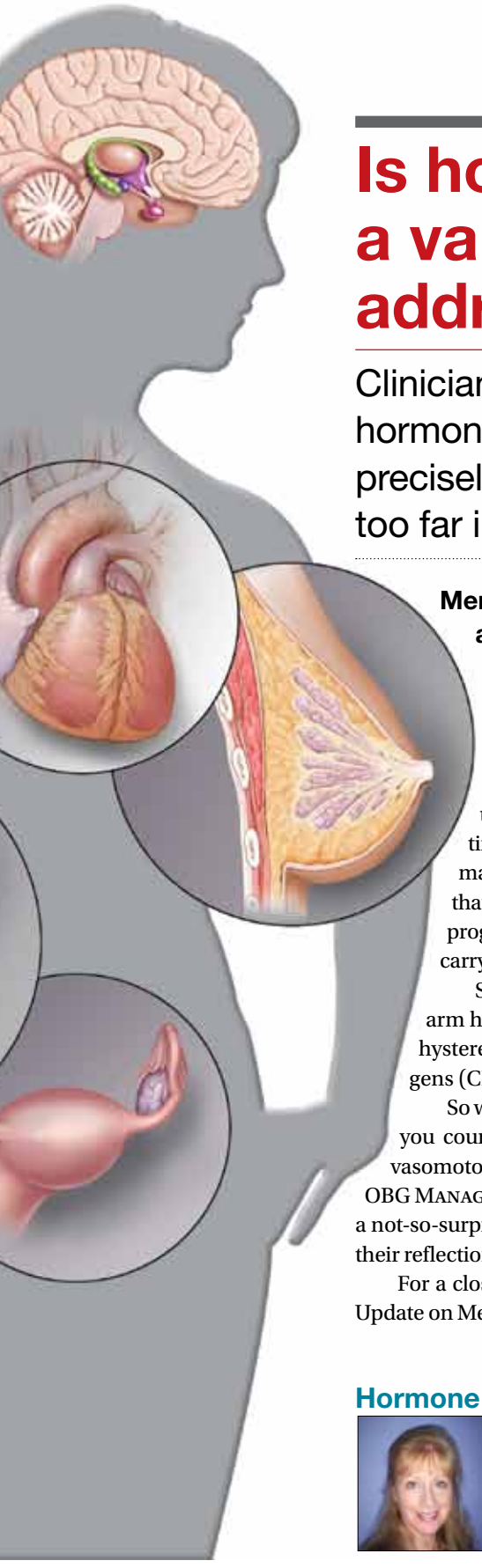

Is hormone therapy still a valid option? 12 ObGyns address this question

Clinicians understand the risks and benefits of hormone therapy for menopausal women more precisely than ever—but has the pendulum swung too far in the direction of risk?

Members of the OBG MANAGEMENT Virtual Board of Editors and Janelle Yates, Senior Editor

When the Women's Health Initiative (WHI) published follow-up data on the association between estrogen-progestin hormone therapy (HT) and breast cancer last fall, it seemed, for a time, like another death knell had sounded for hormonal management of menopausal symptoms.[1] The data showed that breast cancers in women who have used oral estrogen-progestin therapy are more likely to be node-positive and carry a higher death rate than breast cancers in nonusers.

Since then, a new WHI analysis from the estrogen-alone arm has found a *protective* effect against breast cancer among hysterectomized users of unopposed conjugated equine estrogens (CEE).[2]

So what are clinicians to make of all the data? And how should you counsel your menopausal patients who report bothersome vasomotor symptoms? We put these questions to members of the OBG MANAGEMENT Virtual Board of Editors, and they responded with a not-so-surprising diversity of opinion. Presented here are excerpts of their reflections on the role of HT in clinical practice today.

For a closer look at data from the WHI and other studies, see the Update on Menopause, by Andrew M. Kaunitz, MD, on the facing page.

Hormone therapy is alive and kicking

Susan J. Spencer, MD
San Mateo, Calif

To borrow from Mark Twain: Rumors of the death of HT have been greatly exaggerated. With every new spin-off report from the WHI, the tide of panic rises again.

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In my private practice in gynecology, I see many patients who seek my care because another physician (usually another gynecologist) has declined to prescribe HT. Sometimes the HT is refused because the patient has reached 5 years of therapy, and the doctor is simply not comfortable continuing.

What is the guiding principle here? Beneficence? Paternalism (or maternalism)? Risk-aversion? All pharmaceutical therapies have risks. Penicillin can cause anaphylaxis; should we advise patients to avoid antibiotics?

When I counsel women about treatment of vasomotor symptoms, I review herbal and botanical remedies and neurotransmitter modulators as well as estrogen and progestin HT options. I believe that these are all valid options, and I take time to give the patient realistic expectations of efficacy and risks for each one, so that she can make a well-informed decision. But which is the most effective for relief of vasomotor symptoms?

Yes, it's still HT.

In 2011, we have reached an age of enlightenment with regard to HT. We are using lower dosages of estrogen than ever to address menopausal symptoms. We are preferentially prescribing non-oral HT to reduce thromboembolic complications. To prevent endometrial hyperplasia, we are looking to native (dare I say "bioidentical"?) progesterone, as it appears that different progestins carry different levels of breast cancer risk.[3]

An enlightened approach means addressing the patient's symptoms while minimizing the risk of adverse effects. Let's not regress back to the age of panic.

Dr. Spencer reports no relevant financial relationships.

Patients lack information

Judith Volkar, MD
Cleveland, Ohio

As a staff physician in Specialized Women's Health at the Cleveland Clinic, I manage menopausal women on a regular basis. I find that many of these patients—and their physicians—are poorly informed about the actual risks and benefits of HT. They are unaware of the difference between a prevention trial and a risk trial. And they grossly overestimate the risk of an adverse effect. For example, women who used combination estrogen-progestin in the WHI experienced an increase of 8 cases of breast cancer for every 10,000 woman-years of use. In contrast, women who do not exercise regularly suffer an increase of 35 cases of breast cancer for every 10,000 woman-years of use. In short, the use of HT in the average woman poses far less risk of breast cancer than a poor lifestyle does.

Furthermore, women are not aware that we have a great deal of evidence that early initiation of HT minimizes cardiovascular risk. They are unaware that this early initiation of therapy may well confer a decrease in overall mortality as high as 30%. Patients do not realize that the WHI studied only oral HT and that the use of lower-dose transdermal estrogen most likely minimizes the risks of blood clots, stroke, and hypertension.

I believe that we have allowed the sensationalized coverage of the WHI to cloud the actual data showing that the risks of HT are small. There appears to be some gender bias involved. We allow men to have a drug marketed to them that carries a risk of blindness, heart attack, hypertension, and 4-hour erections—we simply conclude that the benefit is worth the risk. Why don't we look at HT in the same risk-benefit light? Perhaps it's because we do not believe that treating a woman's disabling vasomotor symptoms; her silent, progressive bone loss; or her painful vaginal dryness is worthy of our medical attention.

When we approach the problem of hypertension, we do not prescribe the same dosage of the same medication for all patients. Nor do we assume that any medical path is risk-free. My approach to the menopausal patient is the same: I treat her symptoms as I would any other medical condition that I manage. I conduct an individualized risk-benefit assessment, taking into account the patient's family history, cardiovascular and lipid status, and risks of breast cancer and osteoporosis. Each patient is prescribed

"I see many patients who seek my care because another physician has declined to prescribe hormone therapy"
—Susan J. Spencer, MD

a unique dosage individualized for her symptomatology. And I reevaluate the patient routinely and make any necessary adjustment in the drug or dosage, or both.

As clinicians, we are charged with guiding our patients through the media frenzy to help them differentiate reality and hype. Our patients deserve evidence-based management of their real menopausal symptoms.

Dr. Volkar reports no relevant financial relationships.

Some patients demand HT

E. William McGrath Jr, MD
Fernandina Beach, Fla

HT still plays a significant role in my practice. At every annual visit, I review and document the updated risks and benefits of HT for the patient, as well as the alternatives. In recent years, there has been a decline in patient interest in hormones, but it hasn't been as significant as I expected: My patients tend to be more interested in quality of life than the research I quote to them on the complications of HT.

Patients who have new-onset vasomotor instability seldom request HT as first-line therapy. Usually, they request guidance and recommendations for over-the-counter remedies out of concern about and fear of HT. The only patients who specifically request HT are symptomatic patients who have not responded to nonprescription treatment and established patients doing well on HT.

As expected, I have observed a significant increase in symptomatic urogenital atrophy in patients who are not taking systemic HT, so I am prescribing more local vaginal estrogen than ever before.

Despite my annual review of the HT warnings, most of my established patients demand to continue using HT, often commenting, "Doc, are you trying to ruin my marriage?" or "Doc, I need my hormones or I might kill somebody." These particular patients are not fearful of HT—they are fearful of life without it.

"My patients tend to be more interested in quality of life than the research I quote to them on the complications of hormone therapy"
—E. William McGrath Jr, MD

Instant Poll

How do you counsel and treat your menopausal patients who report bothersome vasomotor symptoms?

Go to www.obgmanagement.com to enter your response. Results will be published in an upcoming issue.

As long as HT is FDA-approved and available for use, I will continue to prescribe it for patients when it is appropriate. However, as more potential adverse effects come to light, I am giving strong consideration to having the patient sign a consent form each time I start or renew HT, for obvious liability concerns.

Dr. McGrath reports no relevant financial relationships.

Hormones pose a real legal risk

Peyman Zandieh, MD
Bethpage, NY

I have not prescribed HT since 2002. The reason is simple: No woman is going to sue me for *not* prescribing hormones for menopausal symptoms. She may not be happy. She may switch to another ObGyn. But she will not sue.

Forget about medical literature and scientific data. Every 6 months, it seems, some new article comes out with new recommendations. We ObGyns are like puppets dangling at the end of a string, swinging from one side to another, depending on which way the medical winds blow. Unfortunately, in this day and age, we no longer work for the patients, but for the lawyers.

So heed the following recommendation, and you may get some unhappy patients, but you won't get sued: Do not prescribe hormones for menopausal symptoms. No woman has died from lack of hormones, but all you need is one case of breast cancer, or a fatal heart attack, stroke, or pulmonary embolism, for some lawyer to link the catastrophe to HT, and there goes your practice.

It's just not worth it.

Dr. Zandieh reports no relevant financial relationships.

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Many women turn to alternative therapies

Brian Bernick, MD
Boca Raton, Fla

Many of my patients pursue alternative interventions that do not involve formal estrogen supplementation. These options include both lifestyle changes and phytoestrogens (plant-based supplements with estrogen-like properties). Phytoestrogen products often include black cohosh or soy isoflavones such as genistein that claim SERM-like activity (selective estrogen receptor modulator) to manage hot flashes, night sweats, vaginal dryness, and other menopausal symptoms.

Despite research showing a lack of effectiveness for most phytoestrogen-based products, a surprisingly large percentage of patients utilize these products, often without the knowledge of their provider. It is important to ask about these products because they can interfere with other medications and, in the case of black cohosh, may be contraindicated in patients who have liver disorders.

Although data have been lacking with respect to the use of phytoestrogen-based products, some of these formulations may provide a level of effectiveness for a variety of patients.

Despite the botanical nature of these products, I counsel my patients that there is a potential for estrogen-like activity. Therefore, these products may carry some of the same risks as the estrogen they seek to avoid.

Dr. Bernick reports that he is a consultant for vitaWebMD.

"I explain to my patients that the concept of the lowest dosage for the shortest duration is one we should embrace with all of their medications on a yearly basis"

—Robert delRosario, MD

New data make it easier to tailor HT

Robert delRosario, MD
Camp Hill, Pa

I completed my ObGyn residency during the mid-1990s, at a time when it was common to begin almost every menopausal woman on HT. As data from the WHI trial and Heart and Estrogen/progestin Replacement Study (HERS) exploded in the media, a small percentage of my patients stopped taking their hormones immediately.[4,5] The majority of my patients turned to me for interpretation of the studies and guidance on how they applied to their particular clinical scenario.

I believe that my patients are better served by having an extensive discussion of their general health and behavioral habits as a means of addressing their menopausal symptoms. I must admit, before the WHI and HERS trials, I gave this kind of counseling short shrift. Now, when I talk with patients, I find it easiest to discuss HT from a risk-benefit standpoint in light of the data to date. Before the WHI and HERS trials, I did not treat hysterectomized women any differently than those who had an intact uterus. Nor did I think in terms of initiating treatment in early versus late menopause or pay much attention to risk factors for breast cancer or heart disease. Now, we have data on these considerations that enable me to more accurately determine a woman's unique risk-benefit profile as she contemplates HT. ACOG's analysis and perspective have also helped.[6]

Once beyond this first level of discussion, if the patient elects to initiate HT, the focus shifts to "What dosage and for how long?" At her annual visit, we revisit "the numbers" and discuss how they apply to her case. Most important, I assess how HT is affecting her quality of life. I explain to my patients that the concept of the lowest dosage for the shortest duration is one we should embrace not only with HT but with all of their medications on a yearly basis.

Today, my patients run the spectrum of HT use. I have 80-year-old hysterectomized patients with a 30-year history of HT use who look at me pointedly and say, "You're not gonna stop my hormones, are you?" And I have 52-year-old patients who proudly inform me that their symptoms are manageable without HT now that they have started yoga.

Dr. delRosario reports no relevant financial relationships.

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More patients are declining HT

Mark Schnee, DO
Kansas City, Mo

I routinely advise my patients about the increased risk of breast cancer and positive nodes when I prescribe estrogen-progestin HT, based on the recent publication from the WHI study.[1] I tell them straight up that it is a defined risk, but short-term usage of HT for vasomotor symptoms may be acceptable, along with yearly mammograms. They are comfortable knowing the risks and are declining, in increasing numbers, to start or maintain HT.

Alternatives that I recommend are multivitamins and supplemental vitamin D and daily calcium for osteopenia prevention. I suggest using a serotonin reuptake inhibitor for vasomotor symptom control.

Dr. Schnee reports no relevant financial relationships.

Individualizing therapy is a priority

Raksha Joshi, MD
Long Branch, NJ

I doubt that any gynecologist in active practice has forgotten the day in July 2002 when the startling news about the WHI study broke. I remember clearly that I was inundated with questions from anxious women—as well as my residents—wondering about the immediate implications. Suddenly, what had been a panacea for menopausal vasomotor symptoms had become a deadly poison, and women wanted to know with certainty whether they would develop breast cancer.

Since that time, as small aliquots of new information have been published periodically, we have learned to look at HT in a new light. Not all the news is positive, and not all of it is negative—and we are certainly far from the last word on this controversy.

My practice with a Federally Qualified Health Care Center brings patients of different ethnic and racial groups to my office. Most of them (~55%) have Spanish as their primary language, and a significant minority (~30%) are English-speaking. My patients are generally not forthcoming about symptoms that they consider a "normal" part of menopause. I therefore question perimenopausal and menopausal women specifically about vasomotor symptoms and vaginal dryness and dyspareunia. The options I offer them depend on the most troubling symptoms.

Besides estrogen, I offer fluoxetine and desvenlafaxine for vasomotor symptoms. For vaginal dryness and dyspareunia, I offer short-term local conjugated estrogen cream. My patients tend to be more accepting of the estrogen cream than the antidepressants. For perimenopausal women who also need contraception, I offer the low-dose oral contraceptive. Of course, I also suggest lifestyle adjustments such as avoidance of caffeine and increased physical activity.

Numerous reports have noted that overweight and obese women experience more hot flushes and vasomotor symptoms than their counterparts of normal weight, but I find that thin Caucasian women complain of hot flushes most often. These patients are generally aware of HT but reluctant to use it. Many of these women are taking St. John's wort or black cohosh as self-medication but do not necessarily report this use. Now I specifically ask about these remedies.

In short, I listen actively, take a thorough history, try to be culturally sensitive, and individualize my advice and pharmacotherapy to suit each patient's needs.

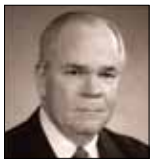
Dr. Joshi reports no relevant financial relationships.

"My patients are generally not forthcoming about symptoms that they consider a 'normal' part of menopause"

—Raksha Joshi, MD

Transdermal and vaginal estrogen are mainstays

Robert L. Shirley, MD
Winchester, Mass



Denying a woman HT when she is suffering from vasomotor symptoms is heartless. I typically recommend vaginal administration of estrogen and progesterone. Reports from the WHI

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suggest that it is best to avoid a first pass through the liver, and oral medroxyprogesterone acetate is implicated in unwanted heart and breast effects of HT, so I generally prescribe transdermal estrogen, the vaginal ring, or estrogen cream to relieve symptoms. A Prometrium capsule inserted vaginally twice a week protects the endometrium nicely. In my practice, an endometrial sample verified benign endometrium in every case of breakthrough bleeding with this program.

If a patient cannot take estrogen because of breast cancer or concerns about it, I typically offer oral gabapentin for vasomotor symptoms and local tamoxifen (one tablet, ground up, with KY jelly, inserted vaginally twice weekly) for symptoms in the pudendal region. This local tamoxifen improves clinical appearance, vaginal pH, and the cytologic cornification index.

Dr. Shirley reports no relevant financial relationships.

A turn away from hormones

Vimal Goyle, MD

Wichita, Kan

Very few of my patients accept hormonal therapy for their menopausal symptoms these days. A couple of patients have asked for bioidentical hormones, and a few others have been candidates for a low-dose oral contraceptive. Some patients ask about blood tests to determine their menopausal status, but they usually agree with me after I explain why these tests are not helpful.

In my practice, the most common menopausal symptom is vaginal dryness—but I usually have to ask about it before the patient acknowledges the problem. I recommend vaginal lubricants more often than local estrogen, and I try to keep a good supply of lubricants on hand.

Overall, patients are fearful of hormones. I try to counsel them that the benefits and risks of hormones vary according to age and route of administration. I rarely prescribe combination estrogen-progestin HT anymore. And I prefer the transdermal route rather than oral administration. In women who have a uterus, I prescribe quarterly progesterone (Prometrium). Otherwise, I recommend unopposed estrogen.

Dr. Goyle reports no relevant financial relationships.

Stress the benefits of HT!

Stanley Franklin, MD

Lewisville, Tex

You only get one shot! One shot to sell symptomatic menopausal women on the benefits and use of estrogen. If you drop the ball by not anticipating and explaining the side effects, your patient will quit and buy the junk over the counter, which is usually worse than useless! If you are a firm believer in the four "S"s of HT—*s*leep, *s*ex, *s*kin, and *s*anity—you must be positive and stress them to your patient.

Sleep is obviously better when the patient doesn't wake up drenched in sweat. *Sex* is better because it doesn't hurt. (Ask your patient whether she would like a plum or a prune for a vagina! She will instantly grasp the physiologic concept!) *Skin* is better because of the slowdown in collagen loss. *Sanity* is improved because of the increase in well being, improved thought processes, and enjoyment of life.

For heaven's sakes, don't stop HT after 5 or 6 years! Keep it going with gels, patches, or intravaginal cream forever. After all, women spend more than one third of their life in the postmenopausal phase—make it a wonderful life! Your patients will be appreciative. More important, they will reward you by coming back to see you year after year and singing your praises.

Dr. Franklin reports no relevant financial relationships.

Scare headlines grab attention

Saul R. Berg, MD

Pittsburgh, Pa

I believe that the tide will turn in regard to

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"Very few of my patients accept hormonal therapy for their menopausal symptoms these days"

—Vimal Goyle, MD

HT in the not-too-distant future. It takes time for the real truth to get out. In the meantime, scare headlines tend to grab attention.

I hope that, in the near future, we will be able to genetically identify women who should not use HT. Until then, I discuss the risks and benefits of HT with my patients and honor their decision. Transdermal estrogen and bimonthly or quarterly progestin—I typically use Prometrium—are my preference.

At present, there don't seem to be any outstanding alternatives to hormonal therapy.

Dr. Berg reports no relevant financial relationships.

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PRODUCT UPDATE

VSCAN OFFERS QUICK-LOOK IMAGING OUTSIDE THE ULTRASOUND SCAN ROOM

GE Healthcare's Vscan is a new, pocket-sized, hand-held ultrasound tool that provides black and white anatomic and color-coded blood flow images. Roughly the size of a smart phone, it is now being used by ObGyns in a clinical setting beyond the ultrasonography room. While **Vscan** is not intended to replace a full fetal ultrasound survey, it has the potential to redefine regular prenatal exams by providing physicians a quick look to assess fetal viability, says the manufacturer. **Vscan** can be used during every step of a pregnancy—from fertility procedures through labor and delivery.

FOR MORE INFORMATION, VISIT www.gehealthcare.com/Vscan

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The new **MiSeal™ Reposable Thermal Ligating System** from **Microline Surgical,** can seal and divide, grasp and dissect soft tissue and vessels using a reusable handle, dual-action jaw, and disposable tips. Proprietary tissue welding technology uses direct thermal energy and focused pressure, offering the clinical benefits of precision, safety and reliability. **MiSeal** minimizes instrument exchange and the risk of collateral tissue damage while providing the economical benefits of a reposable design, says Microline.

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