1. Our current environment is highly litigious, with lawyers advertising their services to patients who have been injured by the use of hormone therapy (HT). In your practice, how do you document the informed consent process for HT? Are consent forms helpful in outlining the established risks and benefits of HT?

Response from Drs. Jan L. Shifren and Isaac Schiff:

We discuss the risks and benefits of HT with our patients in the same way we discuss the risks and benefits of all treatment options we provide. Hormone therapy is an FDA approved treatment for vasomotor symptoms and there should be no concern of legal repercussions when prescribing to appropriate patients for approved indications. We review the findings of the WHI briefly, including a small increase in risk in cardiovascular disease outcomes, but reassure otherwise healthy women that this risk was not seen in women below the age of 59 or within 10 years of menopause. A small, but significant increased risk of breast cancer with HT use of more
than 4–5 years is discussed, which serves as a good time to remind women that their goal will be to use HT at the lowest dose for the shortest time needed. For women without a uterus, we discuss the increased safety of estrogen-alone regimens, with no clinically significant cardiovascular disease or breast cancer risks seen at 7 years of use. We document in the patient’s chart the risks, benefits and alternatives reviewed, as we would when prescribing any medication. A consent form is not necessary.

2. For those patients who choose HT for management of vasomotor symptoms, what is the initial dosage you typically use in your practice? How often should follow-up visits be scheduled? Is there any benefit to increasing the dosage if adequate relief is not achieved? Once her symptoms have been adequately relieved, should the patient be encouraged to follow up sooner than one year to continue the discussion of HT risks and benefits?

Response from Drs. Jan L. Shifren and Isaac Schiff:

We usually give women the choice of starting at a higher dose and then decreasing the dose when they’re feeling well, or starting at a lower dose and then increasing, if their symptoms are not well controlled. Women typically have an opinion on this that we respect. Higher doses include CEE 0.625, oral E2 1 mg, or transdermal E2 0.1 mg; lower doses include CEE 0.3, oral E2 0.5 mg, or transdermal E2 0.05 or 0.025 mg; progestin would be added in a continuous combined or cyclic fashion for women with a uterus. We typically see women approximately 3 months after an initial prescription and then every 3 months until she is on a regimen that’s working well for her. There are so many approved products with varying hormone types, doses, and modes of administration that a regimen should be identified that will provide needed relief and acceptable side effects. If hot flashes do not respond to HT, we often assess thyroid function or seek other causes for her symptoms. Once a woman is doing well, we typically see her yearly for annual care. At this visit, she is encouraged to try to decrease her dose and, once she is doing well at a very low dose, to consider stopping HT to reassess her symptoms.
3. Do you have a preferred method or protocol for weaning patients off of HT?

Response from Drs. Jan L. Shifren and Isaac Schiff:
Although limited studies are available to guide weaning strategies, we believe that slowly decreasing dose and dosing intervals, over months to years, is the best way to wean patients off HT. We typically will give women prescriptions for several doses of HT and encourage them to decrease the dose or dosing interval approximately every 3 months and to let their vasomotor symptoms guide the pace of their wean. Allowing women to control the weaning process is very important, as many of them were very symptomatic prior to starting HT and are fearful of returning symptoms. For example, a woman might be given prescriptions for transdermal E2 0.05 and 0.025 twice weekly patches and be advised to decrease from 0.05 twice weekly, to 0.05 alternating with 0.025 each week, to 0.025 twice weekly, to 0.025 worn only half a week, to stopping treatment.

4. How do you counsel women who have self-discontinued HT out of concerns for the findings of the WHI and now want to resume treatment for vasomotor symptoms? Do you consider this subset of patients to be the same as newly menopausal women? If reinitiated within 5 years of discontinuation do they have the same risks as a newly menopausal woman, regardless of their age?

Response from Drs. Jan L. Shifren and Isaac Schiff:
If a woman who discontinued treatment remains symptomatic and would like to resume HT, she remains an appropriate candidate if she is otherwise healthy and below age 60. Risks increase with increasing age and underlying cardiovascular risk factors, so these decisions need to be individualized.
5. Some patients will argue that bioidentical hormones are more effective because “It is formulated just for me.” Registered pharmacists are compounding and marketing bioidenticals, giving the concept some credibility in the media. What have you found to be the most effective arguments in discouraging their use by a determined, insistent patient?

Response from Drs. Jan L. Shifren and Isaac Schiff:

We see many women influenced by the media and popular talk-show hosts who prefer the message of boundless benefits and no risk with “custom compounded bioidentical HT” to our thoughtful, evidence-based recommendations. We inform these women that “bioidentical” and “natural” are marketing terms, not medical terms, and that custom compounded products receive very little government oversight, so purity, dose, content, and bioavailability are often unknown. We discuss that although these products are likely no safer than others, we will gladly respect her preference by providing FDA approved formulations of the same hormones her ovaries made when she was cycling, the “natural” hormones, estradiol and progesterone. Approved formulations are available for progesterone (Prometrium) and estradiol (pills, patches, gels, spray, vaginal ring), and women are informed that doses of these products will be “customized” to meet their individual needs, optimizing hot flash relief and minimizing side effects.