

ORIGINAL STUDY

Practice patterns and perspectives regarding treatment for symptoms of menopause: qualitative interviews with US health care providers

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Abstract

Objective: To document health care providers' views regarding treatments for symptoms associated with menopause and discussions with patients about symptoms and treatment decisions. Results informed development of a data collection form for a retrospective medical record review (reported separately).

Methods: Registered US gynecologists or primary care providers from all US regions were identified from local association directories and an in-house database and were invited to participate in a qualitative interview if they consulted with three or more patients per week presenting with menopausal symptoms. Participants provided demographic data, information about patients' symptoms, and health care provider and patient views on prescription and nonprescription therapies. Key concepts/themes from interviews were identified.

Results: Participating health care providers (10 gynecologists, 10 primary care providers) agreed there are effective treatment options for menopausal symptoms, particularly vasomotor symptoms and vaginal dryness and/or atrophy. Health care providers reported that treatment was generally dictated by symptoms that interfered with quality of life and/or daily activities, although patients often had symptoms for months before presentation. All health care providers said they prescribe hormone and/or nonhormone therapies for treatment of menopausal symptoms; half stated that they typically inquire about patients' nonprescription therapy use, and 45% recommend specific nonprescription therapies. The most commonly cited barriers to initiation of any therapy for menopausal symptoms were patient concerns about risks and financial considerations (ie, insurance or cost).

Conclusions: US health care providers reported prescribing therapies for menopausal symptoms and noted that these therapies were perceived as generally effective; however, barriers to initiation of prescription therapy exist, and new treatment options are needed.

Key Words: Complementary therapies – Hormone therapy – Hot flashes – Nonhormone therapy – Physician – Prescribing patterns.

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strogen-based hormone therapy (HT) is considered the most effective first-line treatment option for vasomotor ✓ symptoms (VMS; consisting of hot flashes and night sweats) associated with menopause and is also an effective option for vaginal atrophy, which can cause vaginal/vulvar dryness, discharge, itching, and dyspareunia. 1-6 Several guidelines recommend systemic HT for women younger than 60 years or within 10 years of menopause who have bothersome VMS associated with menopause and no contraindications. Local estrogen therapy is recommended for women who have only vaginal symptoms. 1,3,5,6 Thus, depending on age, time since menopause, medical history, and patient preference, HT may not be the right choice for all women. In fact, many women who are perimenopausal or postmenopausal wish to avoid HT,⁷ primarily driven by concerns about an increased risk of cancer and particularly breast cancer.8,9

To date, the only nonhormone prescription medication approved by the US Food and Drug Administration for VMS associated with menopause is low-dose paroxetine, a selective serotonin reuptake inhibitor (SSRI)¹⁰; other SSRIs, serotonin norepinephrine reuptake inhibitors (SNRIs), gabapentin/pregabalin, and clonidine are sometimes used off-label for VMS.²⁻⁵ Current nonhormone therapies (non-HTs) are perceived as having moderate efficacy compared with HT but may have tolerability concerns (eg, dizziness, somnolence/drowsiness, fatigue, dry mouth) or drug interactions.^{2,4,6} Many women therefore opt for over-the-counter (OTC) herbal remedies and dietary supplements—which are not regulated by the US Food and Drug Administration and have uncertain efficacy for VMS and potential safety risks—or nonpharmacologic alternatives and behavioral approaches or lifestyle modifications, for which evidence is mostly limited.^{2-4,11-13}

Although it is widely recognized that use of HT has dramatically declined since the Women's Health Initiative reported that combined estrogen/progestogen therapy increases the risk of breast cancer, stroke, and venous thromboembolism, ¹⁴⁻¹⁸ current US trends in the management of symptoms associated with menopause are not well understood. In addition, the extent to which health care providers (HCPs) discuss, advise, and document the use of nonprescription therapies for VMS is not well characterized.

We conducted qualitative interviews with 20 HCPs in a noninterventional, cross-sectional, observational study documenting HCPs' views and practices regarding prescription and nonprescription treatments for VMS related to menopause. The interviews were designed to inform data collection for a more extensive retrospective review of electronic health records (EHRs) that would identify and describe documented treatments for VMS in US women with menopausal symptoms and their associated health care resource utilization. Results from that EHR review are reported separately in this issue of *Menopause*. ¹⁹

METHODS

Participants

Eligible HCPs were registered US gynecologists (GYNs; including advanced practice providers in gynecology) and primary care providers (PCPs; internal medicine or family physicians, or

advanced practice providers) who routinely consult with or treat at least three patients presenting with symptoms of menopause (including hot flashes) per week. Eligible HCPs also had prescriptive authority and access to and permission to use EHRs via the electronic system used by their practice. Although no EHR data were extracted and captured in this study of physicians' perceptions toward therapy for VMS associated with menopause and their related patient interactions, HCPs provided information on the location of information in their practice's electronic medical chart system to inform design of the electronic data collection form (DCF).

The study was conducted by RTI Health Solutions (RTI-HS; Research Triangle Park, NC), in collaboration with the study sponsor (Astellas Pharma, Inc, Northbrook, IL). Participating HCPs were identified by a subcontractor of RTI-HS (J. Reckner Associates, Inc, Chalfont, PA) using local medical association directories and an in-house database of HCPs who had participated in prior research and consented to future contact. A convenience sampling approach was used to recruit 20 HCPs (10 GYNs, 10 PCPs). Soft quotas were applied to geographic regions for national representation (Northeast, Southwest, West, Southeast, and Midwest) and to practice settings (GYN and PCP). Identified HCPs were sent an e-mail invitation and requested to contact the recruiter if interested in participating. If the HCP met the screening criteria, a study interview was then arranged. Health care providers were compensated for their time.

Study design

A single interview was conducted with each HCP via telephone in May or June 2020. The 60-minute interviews were semistructured, using an interview guide developed by RTI-HS in collaboration with the study sponsor based on study objectives. The interview guide covered key themes and included prompts allowing interviewers to ask additional questions to verify their interpretation of answers, as needed. Two experienced members of RTI-HS, both native English speakers, participated in the interviews with each HCP; one led the interview, and the other took detailed notes.

Interviews were recorded but not transcribed. Participants were reminded that the conversation was being recorded, and verbal consent was obtained from HCPs at the time of the interviews. Each interview was assigned a unique identification number by RTI-HS; no identifying information was collected in the interviews. Audio records were destroyed upon completion of the study. The study was determined by RTI-HS International's institutional review board to meet the criteria for exemption from institutional review board review.

Study endpoints

Each HCP provided demographic information, number of years in practice, specialty, approximate number of patients with VMS treated within a typical week, and type and geographic region of practice. The endpoints captured included the reasons patients present to HCPs for symptoms of menopause (eg, at a specifically scheduled visit or an annual examination), symptoms patients reported and that HCPs inquired about, nonprescription therapies patients reported and that HCPs inquired about

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and/or recommended, HCPs' views on nonprescription and prescription therapies, reasons for treatment initiation, reasons for treatment discontinuation, and the HCPs' perceived barriers to treatment. The questions posed about patients pertained to HCPs' patients in general and not specific individuals.

Data analysis

A sample size of 20 was expected to result in saturation (ie, the point at which no additional insights would be derived²⁰) and be sufficient to guide development of the electronic DCF for the retrospective EHR review.

Characteristics of the participating HCPs were summarized using descriptive statistics. One interviewer created a summary for each interview based on audio recordings and field notes, and the second interviewer checked for accuracy. Interviewers identified key concepts representing HCPs' opinions of treatment and the information they discussed with patients regarding menopausal symptoms and generated themes observed across interviews. Once common themes were identified, representative quotations (based on field notes only) supporting those themes were identified. No statistical comparisons were performed, based on the descriptive nature of the study.

RESULTS

Participant demographics

Of a total of 850 HCPs who were invited by e-mail to participate in the qualitative interviews, 26 responded and were screened. Of the 26 HCPs, 20 (10 GYNs, 10 PCPs) were eligible and participated (two failed to meet the eligibility criteria [did not routinely consult with or treat three or more patients for menopausal complaints; did not use electronic records], two missed interviews, and two were eligible but did not participate because the quota had already been met); none were identified as advanced practice providers. The PCPs included seven family physicians and three internal medicine physicians. Most respondents (65%) were in an office-based private practice, and the mean number of years in practice was 17. Additional characteristics of the participating HCPs are given in Table 1.

Presentation of symptoms of menopause

The interviewed HCPs reported that patients were equally likely to bring menopausal symptoms to their attention at either an appointment scheduled specifically to discuss these symptoms or at a regularly scheduled visit. Most HCPs noted that menopausal symptoms were present for at least a few months, on average, before the patient presented to the HCP (three HCPs said the duration could have been a few years; one HCP said 4-6 weeks). According to HCPs, the symptoms of menopause that most commonly drive their patients to seek medical attention are VMS (90% of GYNs, 100% of PCPs), vaginal symptoms (100% of GYNs, 10% of PCPs), and sleep difficulties (30% of GYNs, 50% of PCPs) (Fig. 1). All HCPs said they inquired about specific symptoms that the patient did not spontaneously report, most commonly VMS; vaginal dryness, atrophy, and/or dyspareunia; problems with sleep; changes in menstruation or mood; and incontinence or pain with urination. Health care providers asked about symptoms of menopause with patients in their late 40s

TABLE 1. Health care provider characteristics

| Characteristics | n = 20 |
|---|-------------|
| Sex, n (%) | |
| Male | 9 (45) |
| Female | 11 (55) |
| Medical specialty, n (%) | |
| GYNs | 10 (50) |
| PCPs | 10 (50) |
| Practice setting, $n (\%)^a$ | |
| Office-based private practice | 13 (65) |
| Hospital based: academic or teaching | 2(10) |
| Hospital based: community | 4 (20) |
| Hospital based: private | 2(10) |
| Not-for-profit outpatient clinic | 1 (5) |
| Region, n (%) | . , |
| Midwest | 4 (20) |
| Northeast | 3 (15) |
| Southeast | 5 (25) |
| Southwest | 3 (15) |
| West | 5 (25) |
| Years in practice (postresidency) | ` ' |
| Mean (SD) | 17 (8.0) |
| Approximate number of patients with menopausal symptoms | ` ′ |
| treated in a typical week | |
| Mean (SD) | 24.5 (17.3) |

^aThe total can be greater than 100% because HCPs can belong to multiple categories (two HCPs worked in community hospitals that were also teaching hospitals). GYNs, gynecologists or advanced practice providers in gynecology; PCPs, internal medicine or family physicians or advanced practice providers in primary care.

or older (nine HCPs), patients who were postmenopause (six HCPs), or patients who presented with a menopause-specific symptom (four HCPs).

Prescription and nonprescription therapies for menopausal symptoms

All providers reported prescribing systemic HT (including oral and transdermal) and SSRIs/SNRIs. All but one of the HCPs (a PCP) said they prescribe vaginal estrogen (Table 2). Eleven HCPs (eight GYNs, three PCPs) said they did not generally limit the duration of systemic HT and had no concerns about keeping patients on therapy as long as needed. The remaining nine HCPs, including two GYNs (20% of GYNs) and seven PCPs (70% of PCPs), reported that they generally prescribed systemic HT for the "shortest possible duration" or withdrew treatment after 5 years based on treatment guidelines. Reasons HCPs gave for limiting duration or discontinuing any HT included adverse events (AEs), inability to afford treatment, patient preference, and patient age. Examples HCPs gave of AEs that limited the duration of or led to discontinuation of HT included abnormal mammogram findings, high blood pressure, deep vein thrombosis, breast tenderness, vaginal bleeding, and weight gain. Lack of symptom relief and AEs were the only reasons HCPs noted for limiting duration of or discontinuing non-HT for menopausal symptoms.

Health care providers reported that only a small proportion of their patients (10%-30%) spontaneously reported the use of nonprescription or complementary therapies for management of menopausal symptoms. Half of the HCPs said they typically inquire about nonprescription therapies, whereas eight said they do not. The two other HCPs noted that the information was captured on the patient's intake form, and they made no direct inquiry.

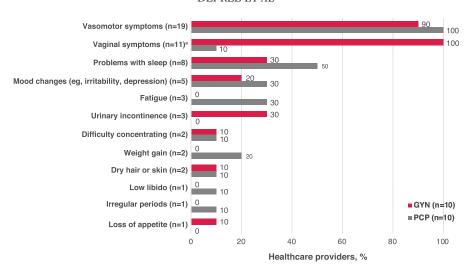


FIG. 1. Health care provider—reported symptoms of menopause most commonly leading women to seek medical attention (n = 20). n values represent number of health care providers who endorsed that symptom as leading women to seek medical attention. ^aVaginal symptoms include vaginal dryness, atrophy, and/or dyspareunia. GYN, gynecologist; PCP, primary care provider.

Beliefs related to prescription treatment options

Nearly all HCPs (95%) agreed that effective treatment options are available for symptoms of menopause, particularly VMS and vaginal dryness and/or atrophy; one PCP asserted that available options are not effective. Hormone therapy specifically was described by HCPs as very effective for symptoms including VMS and vaginal dryness and/or atrophy. Six HCPs (30%) felt there was still room for improvement in current treatments. Specifically, participants stated the following:

They [medications] all serve a purpose, but they... are not going to fix everybody's problems. They may dilute or downplay their symptoms to a point that they are manageable. [Participant 3, PCP]

Atypical therapies [ie, SSRIs, gabapentin, etc] work for certain people, but they don't achieve the same degree of "cure" for these symptoms, so predictability becomes difficult... not an exact science... we have a lot of therapies

[that] may not translate into a cure or fix for everybody... [it's] hard to predict how it'll work for everybody. [Participant 17, GYN]

...we need more, and we need different ones, and we need better insurance coverage. [Participant 9, GYN]

Whereas most HCPs (65%) felt that the range of available treatment options for menopausal symptoms was adequate, four HCPs said that more options would be useful. Six HCPs believed that there were not enough different types of treatment available for menopausal symptoms. Representative comments from these six included:

There are a wide array of products, but we need... more generic alternatives. More choices are always better. There could be more. [Participant 2, PCP]

It would be good to have another class. [Participant 8, PCP]

TABLE 2. Prescription treatments for menopausal symptoms

| Prescription treatments | GYNs (n = 10), n (%) | PCPs (n = 10), n (%) | Total population $(n = 20)$, $n (\%)$ |
|---|----------------------------|----------------------------|--|
| Systemic hormone therapy ^a | 10 (100) | 10 (100) | 20 (100) |
| Selective serotonin reuptake inhibitors or serotonin norepinephrine reuptake inhibitors | 10 (100) | 10 (100) | 20 (100) |
| Localized or local hormone therapy | 10 (100) | 9 (90) | 19 (95) |
| Selective estrogen-receptor modulators | 9 (90) | 6 (60) | 15 (75) |
| Compounded hormone medication ^b | 4 (40) | 7 (70) | 11 (55) |
| Gabapentin | 6 (60) | 5 (50) | 11 (55) |
| Clonidine | 4 (40) | 4 (40) | 8 (40) |
| Pregabalin | 2 (20) | 4 (40) | 6 (30) |

^aThe most common types of systemic hormone therapy prescribed were oral and transdermal medications (eg, patch), followed by topical medications (eg, cream, gel) and intranasal sprays.

^bPrescribed by 80% of health care providers in the Southeast (4/5), 100% in the Southwest (3/3), 40% in the West (2/5), 33% in the Northeast (1/3), and 25% in the Midwest (1/4).

GYNs, gynecologists or advanced practice providers in gynecology; PCPs, primary care providers, internal medicine or family physicians, or advanced practice providers in primary care.

In terms of nonhormone, it would be nice if we had more efficacious therapies, because generally, they are less efficacious to alleviate vasomotor symptoms compared with an estrogen or estrogen-progesterone therapy. [Participant 17, GYN]

Overall, HCPs had mixed views on the bothersomeness of adverse effects associated with treatments they prescribe for symptoms of menopause: half believed adverse effects are a little or not at all bothersome, 25% said they were moderately bothersome, and 25% said they varied from "not at all" to "extremely bothersome," depending on the specific treatment. Health care providers generally believed that HT was well tolerated. Gabapentin and pregabalin were considered to have bothersome adverse effects, and SSRIs were believed to have no adverse effects in some women and mild adverse effects in others.

Beliefs/approaches related to nonprescription or complementary therapies

Some HCPs reported not recommending specific nonprescription pharmacologic therapies, supplements, or complementary therapies because of a lack of efficacy or their own discomfort with these options. However, most HCPs noted that they did not discourage their patients from using these therapies if they chose to do so. Nine HCPs (45%; six GYNs, three PCPs) did recommend particular herbal supplements and/or vitamins and other OTC products for managing specific menopausal symptoms (including VMS and vaginal dryness), particularly when patients did not want to use prescription therapies. Examples of nonprescription products they recommended included black cohosh, primrose oil, hyaluronic acid sodium salt vaginal suppositories (Revaree), and specific brands containing various plant-based and other natural/homeopathic active ingredients (Estroven, Relizen, Tempo with geniVida, and VagiCare).

Six HCPs (30%) recommended complementary approaches to their patients, including nutritional consultation, acupuncture, counseling, and physical therapy, and 15 of 20 HCPs (75%) noted that they were likely to recommend behavioral or lifestyle interventions for managing symptoms of menopause. Examples

of recommended interventions were diet changes, sleep alterations, exercise, massage therapy, and stress reduction techniques. For some HCPs, healthy diet and exercise were general recommendations offered to women whether or not they had symptoms of menopause.

Factors driving treatment selection

Health care providers said they generally provide patients with HT and/or non-HT options for each of the patient's bothersome symptoms, discuss the risks and benefits of each, and provide a recommendation. Most HCPs leave the choice of treatment up to the patient, but a few said they "steered" patients in specific directions. Symptoms that HCPs said typically led to treatment initiation were those that interfered with patients' quality of life and/or daily activities, most commonly VMS, vaginal symptoms, sleep difficulties, mood changes, and urinary symptoms (Fig. 2). Vasomotor symptoms, sleep, and mood changes were reported by more PCPs, and vaginal symptoms and urinary symptoms were reported by more GYNs as symptoms leading to treatment initiation.

The key factors most HCPs (90%) cited in treatment selection were the type and severity of symptoms, medical history, and patient preference. The symptoms for which HCPs said they most commonly recommended systemic HT (if not contraindicated) or local HT were moderate to severe VMS or vaginal symptoms. For other symptoms, HCPs generally prescribed SSRIs or recommended behavior modifications. Health care providers stated that their patients' medical history was a key consideration for the selection of HT versus non-HT, and specific medical factors most cited were personal or family history of breast cancer, absence of the uterus, and patient comorbidities (history of stroke, blood clots, clotting disorders, thrombosis, pulmonary embolism, and cardiovascular disease [including uncontrolled hypertension]) including smoking status. Most HCPs also weighed patient preference for HT versus non-HT in their selection. Two physicians (both PCPs) said they typically recommend behavior modifications, such as lowering house temperature, dressing in layers, sleeping under a fan, and using OTC lubricants for vaginal dryness, before prescribing medication.

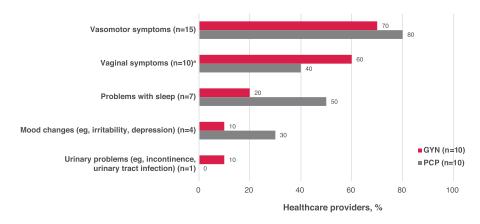


FIG. 2. Menopausal symptoms leading to treatment initiation (n = 20). n values represent number of health care providers who endorsed that symptom as leading to treatment initiation. a Vaginal symptoms include vaginal dryness, atrophy, and/or dyspareunia. GYN, gynecologist; PCP, primary care provider.

Among factors that drive their patients' treatment decisions, most HCPs said their own recommendations and/or advice or the experiences of friends or family members were influential (Fig. 3). Only two HCPs said efficacy was a driving factor for patients' choices (one PCP and one GYN). Lifestyle and cost were reported by more GYNs, and risk factors, patient perceptions, and advice from family and friends were reported by more PCPs as factors influencing treatment selection. Most commonly cited patient-related barriers to treatment (as noted by the HCPs) were patient perceptions/concerns about risks (80% of GYNs and 90% of PCPs) and cost/insurance coverage (60% of GYNs and 90% of PCPs) (Fig. 4).

DISCUSSION

Results from this study provide insight into clinical practice patterns and HCP beliefs related to the management of menopausal symptoms. Initiation of treatment was dictated mainly by symptoms that interfered with a patient's quality of life and/or daily activities, most often VMS, vaginal symptoms, and sleep difficulties. Nonetheless, HCPs said patients often waited several months before bringing these symptoms to their attention, either at an appointment scheduled specifically to discuss those symptoms or during routine visits.

These interview data were used to inform the development of an electronic DCF, which was then used by 283 HCPs to extract data from the EHRs of 1,016 patients with symptoms of menopause, including bothersome VMS. Findings from that retrospective EHR review are published separately. Results from the chart review confirm the accuracy of physician perceptions about menopausal symptoms and the delay in presentation for care, as noted in the interviews. The chart review showed that VMS, sleep problems, and vaginal dryness were the most common symptoms of menopause at presentation and that symptoms were present for at least 6 months before the recorded visit in approximately half of the patients. For patients in the chart review, symptoms of menopause were the primary reason for the visit for 50% of patients.

Health care providers who participated in the interviews agreed that there are effective treatment options available for menopausal symptoms, particularly for VMS and vaginal dryness and/or atrophy, but still felt it would be valuable to have

additional treatment options. Similarly, in a qualitative survey of 22 GYNs and PCPs published in 2009, respondents expressed frustration with the limited non-HT options for women who are not candidates for HT.⁹

All of the GYNs and PCPs in the qualitative interviews said they prescribe HT and/or SSRIs for treatment of menopausal symptoms. Their reports that treatment initiation is generally driven by the presence of symptoms that interfere with a patient's quality of life and/or daily activities are consistent with previously published interview responses from Australian HCPs who said that HT should be offered when symptoms of menopause severely impair quality of life (GYNs: 3/10, PCPs: 5/10, pharmacists: 5/10).²¹ However, it should be noted that not all women who report menopausal symptoms to their HCPs receive prescription treatment, as evidenced by the subsequent expanded chart review, which found that 60.1% of women with menopausal complaints were prescribed treatment, 13.1% had no treatment of any kind documented, and 26.8% had only nonprescription therapies listed. ¹⁹ The chart review indicated that patients of GYNs more commonly had prescription medications documented (63.5% of GYN patients vs 56.7% of PCP patients), which was driven by higher rates of prescriptions for HT (76.3% vs 63.6% of patients with any prescription) and compounded HT (17.2% vs 7.0%).¹⁹ Rates of prescriptions for SSRIs (10.8% vs 18.9%) and SNRIs (1.8% vs 11.9%) documented in the charts were lower among GYNs compared with PCPs, respectively. Similarly, an analysis of 2013-2015 data from women who were postmenopause who participated in the Survey of Midlife in the United States II found three times greater odds of using HT among women who had ever seen a GYN, after controlling for other factors (odds ratio, 3.48; 95% confidence interval, 2.21-5.49; P < 0.0001).²²

In the qualitative interviews, most HCPs said they leave the choice of treatment up to their patients, which is consistent with findings from the 2014 qualitative survey. Nonetheless, most felt that their own recommendations were among the most influential factors in patient treatment decisions, followed by the advice or experience of family and friends. Most common barriers to treatment cited in this qualitative study were patient beliefs/concerns about possible risks of HT (such as fear of cancer or endometriosis) and financial considerations (lack of insurance/high cost). Consistent with the perceptions of physicians in the

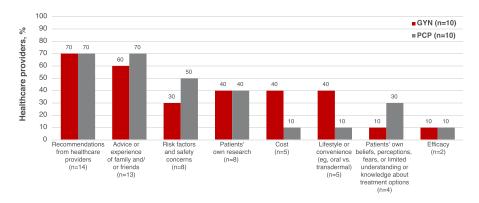


FIG. 3. Health care provider—reported factors that drive patients' treatment decisions (n = 20). n values represent number of health care providers who reported that factor as driving patients' treatment decisions. GYN, gynecologist; PCP, primary care provider.

HCP PERSPECTIVES ON MENOPAUSE CARE

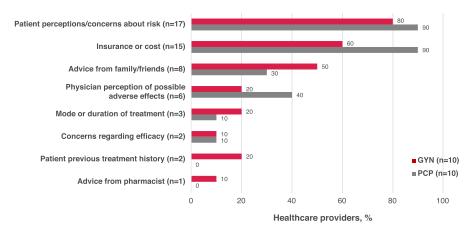


FIG. 4. Health care provider—perceived patient-related barriers to treatment (n = 20). n values represent number of health care providers who reported that factor as being a patient-related barrier to treatment. GYN, gynecologist; PCP, primary care provider.

qualitative interviews, SWAN study participants previously reported provider advice to be one of the most common reasons they initiated HT for symptoms of menopause, second only to symptom relief; however, in contrast to physician perceptions of the strong influence of family/friends, approximately only 10% of SWAN participants who started HT in the years after the Women's Health Initiative safety findings said they did so because of the advice of a friend.¹⁶

A majority (70%) of PCPs—but only 20% of GYNs—who participated in the qualitative interviews said they limit the duration of systemic HT to the "shortest possible duration" or withdrew treatment after 5 years, which they said was based on treatment guidelines. A qualitative analysis, published in 2007, of interviews with 200 GYNs and PCPs in a large Midwestern health maintenance organization reported that 5 years was the median and mode for longest time the HCPs felt women should receive HT.²³ It should be noted that whereas some guidelines (eg, American College of Obstetricians and Gynecologists, American Association of Clinical Endocrinologists) recommend using the lowest effective dose for the shortest duration needed to relieve symptoms, most currently recommend individualizing the duration rather than routinely discontinuing systemic estrogen based on age or duration of use.¹⁻⁵

Half of the HCPs interviewed typically inquire about patients' nonprescription therapy use. Most said they do not discourage their use, and 45% recommend specific nonprescription therapies, including black cohosh. Use of such therapies seems to be common. In the subsequent chart review, 62.4% of patients had nonprescription therapies for menopausal symptoms documented; black cohosh was recorded for 18.7%. 19 These rates are likely to be underestimates, given that not all HCPs inquire about their use, and black cohosh was rarely initiated based on discussion with the HCP (18 [9.5%] of 190 users). 19 In an Australian study, most HCPs (4/10 general practitioners, 7/10 GYNs, and 8/10 pharmacists) expressed concern about the limited evidence of efficacy of nonprescription therapies, and some attributed the effects of these agents to placebo effect; however, 7 of 10 Australian PCPs similarly said that complementary and alternative medicine nonetheless "have a role" and do not discourage their use. 21 Six of 10 pharmacists in that study specifically recommend such therapies to clients for managing symptoms of menopause. ²¹ Almost half (42%) of US HCPs in the survey of the large Midwestern health maintenance organization found complementary/ alternative therapies to be useful or extremely useful, and black cohosh was among the nonprescription therapies that HCPs recommended for treatment of VMS and dyspareunia. ²³ A Cochrane meta-analysis published in 2012 did not find sufficient evidence to support use of black cohosh for symptoms of menopause, ²⁴ and current (2015) treatment guidelines on non-HT do not recommend black cohosh based largely on the findings of that meta-analysis. ^{12,13} More recent meta-analyses suggest black cohosh may have some efficacy in reducing symptoms of menopause. ^{25,26}

Limitations and strengths

The findings from this study should be considered in the context of several limitations. Response summaries were based on a small sample size (although 20 interviews were considered sufficient to achieve saturation), and the acceptance rate for the invitation was low (26/850 invitees responded and were screened). In addition, the sample was limited to US practitioners, so practice patterns, perspectives, and treatment barriers described may not be generalizable to HCPs in other regions and health care systems. Further, the convenience sampling approach can result in sampling bias. Finally, HCP reports of patients' beliefs/preference may not accurately reflect actual patient beliefs/preferences. The inclusion of both GYNs and PCPs in the sample and their geographic diversity across the United States are strengths of this study.

CONCLUSIONS

Based on qualitative interviews with 20 GYNs and PCPs, interference of menopausal symptoms with quality of life or daily activities is a main reason that women seek treatment for these symptoms. All PCPs said they prescribe HT and SSRIs/SNRIs for symptoms associated with menopause and perceive these treatments to be generally effective for relief of such symptoms. Health care provider-perceived barriers to initiation of such therapy include patient beliefs/perceptions, concerns about risks of

treatment, and financial considerations. These findings helped inform data collection for a large EHR review examining treatment of US women with symptoms associated with menopause, which are published separately in this issue, ¹⁹ and provide a resource for designing future studies in this area.

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REFERENCES

- The NAMS 2017 Hormone Therapy Position Statement Advisory Panel. The 2017 hormone therapy position statement of The North American Menopause Society. *Menopause* 2017;24:728-753. doi: 10.1097/gme.0000000000000921
- ACOG practice bulletin no. 141: management of menopausal symptoms. Obstet Gynecol 2014;123:202-216. doi: 10.1097/01.AOG.0000441353.20693.78
- Stuenkel CA, Davis SR, Gompel A, et al. Treatment of symptoms of the menopause: an Endocrine Society Clinical practice guideline. J Clin Endocrinol Metab 2015;100:3975-4011. doi: 10.1210/jc.2015-2236
- Goodman NF, Cobin RH, Ginzburg SB, Katz IA, Woode DE. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of menopause. *Endocr Pract* 2011; 17(suppl 6):1-25. doi: 10.4158/ep.17.s6.1
- de Villiers TJ, Hall JE, Pinkerton JV, et al. Revised global consensus statement on menopausal hormone therapy. *Maturitas* 2016;91:153-155. doi: 10.1016/j.maturitas.2016.06.001
- Neves-E-Castro M, Birkhauser M, Samsioe G, et al. EMAS position statement: the ten point guide to the integral management of menopausal health. *Maturitas* 2015;81:88-92. doi: 10.1016/j.maturitas.2015.02.003
- Marlatt KL, Beyl RA, Redman LM. A qualitative assessment of health behaviors and experiences during menopause: a cross-sectional, observational study. *Maturitas* 2018;116:36-42. doi: 10.1016/j.maturitas.2018.07.014
- French LM, Smith MA, Holtrop JS, Holmes-Rovner M. Hormone therapy after the Women's Health Initiative: a qualitative study. *BMC Fam Pract* 2006;7:61. doi: 10.1186/1471-2296-7-61
- Nekhlyudov L, Bush T, Bonomi AE, Ludman EJ, Newton KM. Physicians' and women's views on hormone therapy and breast cancer risk after the WHI: a qualitative study. Women Health 2009;49:280-293. doi: 10.1080/ 03630240903158446
- 10. Brisdelle [package insert]. Roswell, GA: Sebela Pharmaceuticals, Inc; 2021.
- Guo PP, Li P, Zhang XH, et al. Complementary and alternative medicine for natural and treatment-induced vasomotor symptoms: an overview of systematic reviews and meta-analyses. *Complement Ther Clin Pract* 2019;36:181-194. doi: 10.1016/j.ctcp.2019.07.007
- Mintziori G, Lambrinoudaki I, Goulis DG, et al. EMAS position statement: non-hormonal management of menopausal vasomotor symptoms. *Maturitas* 2015;81:410-413. doi: 10.1016/j.maturitas.2015.04.009

- The North American Menopause Society. Nonhormonal management of menopause-associated vasomotor symptoms: 2015 position statement of The North American Menopause Society. *Menopause* 2015;22:1155-1174. doi: 10.1097/GME.0000000000000546
- Manson JE, Chlebowski RT, Stefanick ML, et al. Menopausal hormone therapy and health outcomes during the intervention and extended poststopping phases of the Women's Health Initiative randomized trials. *JAMA* 2013;310:1353-1368. doi: 10.1001/jama.2013.278040
- Chlebowski RT, Anderson GL, Aragaki AK, et al. Association of menopausal hormone therapy with breast cancer incidence and mortality during long-term follow-up of the Women's Health Initiative randomized clinical trials. *JAMA* 2020;324:369-380. doi: 10.1001/jama.2020.9482
- Crawford SL, Crandall CJ, Derby CA, et al. Menopausal hormone therapy trends before versus after 2002: impact of the Women's Health Initiative Study Results. *Menopause* 2018;26:588-597. doi: 10.1097/ gme.000000000001282
- Sprague BL, Trentham-Dietz A, Cronin KA. A sustained decline in postmenopausal hormone use: results from the National Health and Nutrition Examination Survey, 1999-2010. Obstet Gynecol 2012;120:595-603. doi: 10.1097/AOG.0b013e318265df42
- Ameye L, Antoine C, Paesmans M, de Azambuja E, Rozenberg S. Menopausal hormone therapy use in 17 European countries during the last decade. *Maturitas* 2014;79:287-291. doi: 10.1016/j.maturitas.2014.07.002
- DePree B, Houghton K, Shiozawa A, et al. Treatment and resource utilization for menopausal symptoms in the United States: a retrospective review of real-world evidence from US electronic health records. *Menopause* 2023; 30:XXX-XXX.
- Vasileiou K, Barnett J, Thorpe S, Young T. Characterising and justifying sample size sufficiency in interview-based studies: systematic analysis of qualitative health research over a 15-year period. *BMC Med Res Methodol* 2018;18:148. doi: 10.1186/s12874-018-0594-7
- Davis SR, Herbert D, Reading M, Bell RJ. Health-care providers' views of menopause and its management: a qualitative study. *Climacteric* 2021; 24:612-617. doi: 10.1080/13697137.2021.1936486
- McCarty ME, Thomas HN. Differences in patient-reported hormone therapy use for menopause symptoms by provider specialty. *Climacteric* 2021; 24:600-604. doi: 10.1080/13697137.2021.1945026
- Rolnick SJ, Jackson J, Kopher R, Defor TA. Provider management of menopause after the findings of the Women's Health Initiative. *Menopause* 2007;14:441-449. doi: 10.1097/GME.0b013e31802cc7bc
- Leach MJ, Moore V. Black cohosh (*Cimicifuga* spp.) for menopausal symptoms. *Cochrane Database Syst Rev* 2012;9:CD007244. doi: 10.1002/14651858. CD007244.pub2
- Sarri G, Pedder H, Dias S, Guo Y, Lumsden MA. Vasomotor symptoms resulting from natural menopause: a systematic review and network meta-analysis of treatment effects from the National Institute for Health and Care Excellence guideline on menopause. *BJOG* 2017;124:1514-1523. doi: 10.1111/1471-0528.14619
- Castelo-Branco C, Gambacciani M, Cano A, et al. Review & meta-analysis: isopropanolic black cohosh extract iCR for menopausal symptoms—an update on the evidence. *Climacteric* 2021;24:109-119. doi: 10.1080/13697137.2020. 1820477