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## PERSONAL PERSPECTIVE

# Menopause preparedness: perspectives for patient, provider, and policymaker consideration

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### Abstract

**Objective:** The aim of the study was to identify priorities to address unmet needs in clinical care, education, and access to treatment to improve quality of life for individuals during the menopause transition.

*Methods:* The Society for Women's Health Research convened a working group of 13 experts to discuss updates in research, clinical practice, and policy on menopause. Participants included patient advocates, policy leaders, and clinical specialists and researchers from gynecology, reproductive endocrinology, psychiatry, and epidemiology. Overarching themes and recommendations for improving menopause care were identified and determined by consensus agreement of the participants at the conclusion of the meeting.

**Results:** The Society for Women's Health Research Menopause Working Group identified gaps in clinical care, policy, and patient and provider education. Limited understanding of menopause by patients and clinicians contributes to delays in recognizing the menopause transition and engaging in symptom management. Recent studies on hormone therapy and alternative treatment options provide evidence to inform updates on existing policy recommendations and coverage.

**Conclusions:** To improve care and quality of life for individuals during the menopause transition and after menopause, the working group recommends developing a more standardized approach to menopause preparedness that includes education for both patients and providers, as well as considering policy solutions to address regulatory barriers to care. Providers also need to factor in the diverse needs of individuals experiencing menopause in the development of their personalized care.

*Key Words:* Genitourinary syndrome of menopause – Menopause education – Menopause transition – Policy – Vasomotor symptoms – Women's midlife health.

he menopause transition is characterized by fluctuations and subsequent reduced production of the ovarian hormones estrogen and progesterone and the cessation of a woman's menstrual cycle. Defined as 12 months after the last period, the onset of the

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postmenopause typically occurs in a woman's 40s or 50s, with the average age of the final menstrual period in the United States being 51 years. An estimated 6,000 women in the United States reach menopause daily. Some individuals may experience early menopause before the age of 40 years due to certain illnesses and conditions that affect ovarian function, such as primary ovarian insufficiency and surgical removal of the ovaries, or other risk factors, including family history, smoking, and chemotherapy.

For many individuals, the hormonal changes that take place during perimenopause, the years leading up to menopause, are associated with physical and psychological symptoms such as irregular menstrual cycles, hot flashes, vaginal dryness, mood fluctuations, sleep disruptions, and cognitive challenges. Symptoms vary widely between individuals and are commonly misdiagnosed, resulting in delays in appropriate management of symptoms and disruption of day-to-day activities. Accumulating science about the menopause transition has revealed that this period can last up to 20 years. Some postmenopausal women are also at heightened risk for serious health conditions that increase after the final menstrual period, such as cardiovascular disease,

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**TABLE 1.** Society for Women's Health Research Menopause Roundtable participants

Irene O. Aninye, PhD (Moderator), Director of Science Programs, Society for Women's Health Research

Omisade Burney-Scott, Founder, Black Girls' Guide to Surviving Menopause

CheMyong Jay Ko, PhD, Professor, Comparative Biosciences, University of Illinois at Urbana-Champaign

Nina Coslov, MBA, Founder, Women Living Better

Karen Giblin, President, Red Hot Mamas North America

Shiying Jin, PhD, Assistant Professor, Buck Institute for Research on Aging

Pauline M. Maki, PhD, Professor, Psychiatry, Psychology, and Obstetrics and Gynecology, University of Illinois at Chicago

Sabrina K. Sahni, MD, NCMP, Clinical Assistant Professor, Cleveland Clinic Florida

Philip Sarrel, MD, Emeritus Professor, Obstetrics, Gynecology, Reproductive Sciences, and Psychiatry, Yale University; President, Advancing Health After Hysterectomy Foundation

Lisa Satterfield, MS, MPH, Senior Director of Health Economics and Practice Management, American College of Obstetricians and Gynecologists Jan L. Shifren, MD, NCMP, Vincent Trustees Professor of Obstetrics, Gynecology, and Reproductive Biology, Harvard Medical School; Director,

Midlife Women's Health Center, Massachusetts General Hospital Arianna Sholes-Douglas, MD, FACOG, Founder, Tula Wellness, LLC

Erwin Tan, MD, Director, Thought Leadership—Health, American Association of Retired Persons

Rebecca C. Thurston, PhD, Pittsburgh Foundation Chair and Professor of Psychiatry, Psychology, and Epidemiology, University of Pittsburgh

osteoporosis, and diabetes.<sup>3</sup> Furthermore, because of increases in life expectancy, a woman's postmenopause phase may comprise up to 40% of her life.<sup>1</sup> If an individual is not adequately prepared and/or symptoms are not well-managed, the menopause transition has the potential to exacerbate conditions that impair quality of life and life expectancy.

Knowledge gaps persist in elucidating the genetic, biological, and environmental factors that influence the onset of menopause, symptom presentation, and comorbidities. Gaps in menopause research are not surprising, as gender biases in federal funding demonstrate that conditions predominantly affecting women are typically underfunded relative to patient burden. 4 Menopause also appears neglected when compared to other women's health conditions. The National Institutes of Health (NIH) Research Portfolio Online Reporting Tools system allows users to determine annual research investment by condition or disease category. Even though 100% of women living into late life will experience menopause, it is not one of the 292 listed topics, unlike other reproductive health conditions such as pregnancy or infertility. A search of NIH grants funded in 2019 revealed only 28 project titles that included the term "menopause" or some variation, compared to more than 300 that included "pregnancy" in the title. To address knowledge gaps in the field, federal investment in menopause research must be better tracked and prioritized.

Along with increased attention to research investment, addressing unmet needs in menopause care will require expanding accessibility to treatment options, updating clinical approaches, and improving patient and provider awareness and education.

#### **METHODS**

The Society for Women's Health Research (SWHR) held an interdisciplinary roundtable meeting to (1) assess the state of the science on menopause and reproductive aging; (2) develop recommendations to advance research, symptom management and clinical care, and improve patient and provider education; and (3) discuss policy strategies to improve quality of care for menopause patients. The SWHR Menopause Roundtable participants included clinicians and researchers with expertise in reproductive physiology and endocrinology, gynecology, midlife women's health, behavioral health, and epidemiology; patient advocacy leaders; and professionals with experience in the policy landscape concerning menopause (Table 1). Collectively, the participants in the SWHR Menopause Working Group were selected to represent diversity in training, background, area of expertise, and geographic location.

The roundtable consisted of a series of sessions that provided updates on the research, clinical practice, public health impacts, and relevant public policy concerning menopause, based on priority areas defined by the experts before the meeting. Using a discussion guide, an SWHR moderator engaged participants in contributing data and experiences that supported and/or challenged the information presented. The working group reached a consensus concerning the overarching themes and priority areas of need to address barriers in patient care that are discussed in this article (Table 2).

To present a concise update on the science and policy that reflected the discussions of the working group, a thematic overview of menopause literature was conducted. PubMed and Google were searched for articles published from 2015 to present and for seminal work on the following topics: menopause symptoms, disease burden, comorbidities, hormone therapy (HT) and other treatments, insurance coverage, and workplace accommodations. When appropriate, relevant review articles, position statements, clinical guidelines, and federal reports were included.

**TABLE 2.** Priority recommendations to improve patient quality of life during and after the menopause transition

View menopause as a normal part of life, not as a deficiency or a disease

Prepare women early (as young as age 35) for better overall health during the menopause transition and postmenopause (eg, cardiovascular health, genitourinary health, bone health, mental health)

Explore alternative interventions (eg, medical, nonpharmacologic, and lifestyle) to address a whole-person perspective for individualized care Gather additional data to address menopause-related health disparities and better inform insurance coverage, affordability, access, and education/awareness Develop interdisciplinary cross-sector coalitions to address individual and systemic needs in the healthcare and workforce landscapes

## Addressing regulatory barriers to care

Historically, menopause has been characterized primarily by the decline of estrogen, which has placed a focus on symptom management with HT. In 2002, the Women's Health Initiative study examined the effectiveness of HT for chronic disease prevention in women whose average age was older than 60 years and found an increased risk of coronary heart disease, invasive breast cancer, stroke, and venous thromboembolism in postmenopausal women who took combined estrogen-progestin therapy.<sup>5</sup> As a result, patient use and provider prescription of HT significantly decreased. The next year, the US Food and Drug Administration (FDA) announced that all drugs containing estrogen or estrogen and progestin must include a "black box" label, warning patients of cardiovascular risks and increased likelihood of breast cancer.

Since the initial Women's Health Initiative publication in 2002, further analyses have shown that risks associated with HT use are significantly modified by age, years since menopause, underlying health status, transdermal versus oral administration, and whether estrogen is used alone or combined with a progestogen (in women with a uterus). Experts have concluded that systemic HT is an appropriate treatment for moderate to severe menopause symptoms, especially in healthy women younger than 60 years.

After menopause, genitourinary symptoms (eg, dryness, painful sex, burning, irritation, and urinary incontinence) become a predominant concern that requires increased attention from healthcare providers. Genitourinary syndrome of menopause (GSM) occurs in 50% to 70% of postmenopausal women, and unlike vasomotor symptoms (VMS) that improve with time, GSM typically worsens with aging and lasts years beyond the menopause transition. If left untreated, this chronic condition can become progressively worse. The use of very low-dose vaginal estrogen therapy is a highly effective treatment for GSM, without the need for systemic HT. Early diagnosis and increased access to appropriate hormone and other therapies to treat GSM symptoms would be a widely impactful approach to improving postmenopausal quality of life.

In addition, low doses of estrogen applied directly to the vagina for the treatment of vaginal dryness and dyspareunia are minimally absorbed and do not appear to increase risk for cardiovascular disease or cancer. Despite academic and clinical commentary that the black box warning, as written, lacks evidence to support it and has a deleterious effect on patient health, the FDA has yet to alter or remove this warning on low-dose vaginal estrogen products. Continued conversations with the FDA on this topic represent an important area for regulatory intervention toward ensuring better access to care for postmenopausal patients.

In 2017, the US Preventive Services Task Force (USPSTF), an independent volunteer group of medical experts authorized by Congress and funded through the Agency for Healthcare Research and Quality, issued a public recommendation against the use of combined estrogen and progestin HT or

estrogen-alone therapy for primary prevention of chronic conditions in postmenopausal patients. 13 The issue was given a D rating for "moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits." The recommendation notes that it does not apply to women who are considering HT for the management of menopausal symptoms. Menopause experts have outlined the harms of the USPSTF rating, suggesting the review misinterpreted or misstated research on HT. 14 The 2020 Scientific Statement of the American Heart Association highlighted the menopause transition as a major risk factor for cardiovascular disease and cited evidence for cardiovascular benefits when HT is initiated early among women with premature or surgical menopause and within 10 years of menopause in women with natural menopause. 15 While researchers continue to investigate the role for HT in prevention of cardiovascular disease, osteoporosis, GSM, and other women's health issues, the emphasis is also needed on educating women and healthcare providers about HT as an effective and safe option for healthy women younger than 60 years with bothersome menopausal symptoms.

Physician familiarity and adherence to USPSTF guidelines is mixed, but perhaps more significantly, the majority of health plans use USPSTF recommendations to drive reimbursement decisions. 16 Centers for Medicare and Medicaid Services coverage aligns in reasonable parallel with USPSTF recommendations, and the Patient Protection and Affordable Care Act. passed in 2010, permits revocation of Medicare reimbursement for services given D ratings by the USPSTF. The USPSTF reviews its previous recommendations every 3.5 years and is currently in the process of reviewing its HT recommendations. 17 The task force should carefully examine the impact of its 2017 recommendations on patients and providers and ensure that its updated recommendation addresses the concerns noted by experts. This in turn may be helpful in requesting that Centers for Medicare and Medicaid Services engage in a new National Coverage Determination, as HT coverage for older women merits reconsideration. Insurance coverage of menopause HT in older women for the treatment of bothersome VMS and GSM should remain a covered service, as this is for treatment of a medical condition, not for prevention of disease. This coverage is particularly important given evidence that VMS endure much longer than previously thought, with more than 33% of women experiencing severe VMS 10 or more years after the final menstrual period.<sup>18</sup>

## Remodeling clinical care approaches

While systemic pharmacologic approaches can help some women with menopausal symptoms, <sup>19</sup> nonpharmacologic interventions may be appropriate for those who cannot or choose not to take systemic medications. <sup>20,21</sup> Over-the-counter vaginal lubricants and moisturizers can be helpful for managing genitourinary symptoms by maintaining hydration and relieving dryness and dyspareunia. <sup>22</sup> Many postmenopausal women use herbal remedies, such as phytoestrogen supplements, black cohosh, and red clover extract to manage

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VMS; however, studies of these products and evidence supporting their efficacy and long-term safety are limited and inconsistent.<sup>23</sup> Behavioral approaches can also be used in conjunction with pharmacotherapy to manage menopausal symptoms, but this is also an area that warrants further research. Existing data indicate that structured physical activity, yoga, and similar exercises are some lifestyle interventions that many women have employed to improve perimenopausal and postmenopausal quality of life; however, their impact on menopausal symptoms vary according to the specific intervention and the specific symptom.<sup>24</sup> For example, aerobic exercise is an important approach to managing mood,<sup>25</sup> but has not proved to be effective for managing VMS. 26 On the other hand, cognitive behavioral therapy and mindfulness-based therapies are often effective in managing the bother and interference associated with VMS. 22,27,28 Furthermore, cognitive behavioral therapy is an evidencedbased approach to treating insomnia, including in women with VMS.<sup>29</sup> Ongoing empirical evaluation of behavioral and other non-pharmacologic approaches to symptom management is important to provide women with a range of options to manage their symptoms.

Hormonal changes associated with menopause can also catalyze manifestation of underlying conditions. For example, as a key regulator of bone remodeling, estrogen promotes building bone mass and protects against osteoporosis and increased risk of fracture that are sometimes observed after menopause. Aging women are at increased risk for dyslipidemia, hypertension, cardiovascular disease, and diabetes mellitus, and research is ongoing regarding the contribution of hormone changes and other menopause-related physiologic changes to these problems. Menopause and aging can also be associated with adverse changes in cognition, skin, sleep, and mental health. To address these potential health risks, early interventions to improve patient care should not be limited just to menopause symptom management but include preventive healthcare measures.

To promote health and wellness during the menopausal transition and postmenopause, healthcare providers should initiate conversations with patients before this midlife transition begins. Successful implementation of this approach requires addressing knowledge gaps among healthcare providers concerning menopause. Training in menopause is not a routine part of medical school curricula or residency training. and the negative consequences of this educational gap on women have been recognized for some time.<sup>31</sup> Provider training could help to limit the use of custom compounded hormone products that are not regulated by the FDA and that lack evidence of safety or efficacy.<sup>32</sup> Improved medical curriculum on menopause is needed not only for obstetricians and gynecologists, but also for the spectrum of healthcare providers who see women in midlife, including primary care and mental health professionals. Without menopause-specific education, providers can easily misunderstand or dismiss menopause symptoms related to irregular menstrual cycles or heavy bleeding, mood, vaginal symptoms, and disordered sleep. A patient's age, gender identity, and type and stage of menopause are all integral factors that affect how symptoms present and the associated risk for additional health conditions.<sup>33</sup> Providers must understand how to treat symptoms across diverse populations and develop a personalized care plan for each individual.<sup>34</sup>

## Shifting the menopause paradigm

Promoting menopause preparedness for patients and providers requires prioritizing patient awareness, education, and empowerment before the menopause transition, starting as early as 35 years. Increasing public knowledge about menopause-related issues will help challenge the stigma associated with aging and menopause, and help individuals identify and attain assistance with menopausal symptoms.<sup>35</sup> When planning for or experiencing pregnancy, established healthcare and policy systems offer ample opportunities for individuals and their families to establish a regular medical care routine, attend birthing and breastfeeding classes, and engage with support networks to ensure optimal preparedness for this transformative life stage. These interventions have been instrumental in improving maternal and infant health and reducing pregnancy-related mortality and morbidities. Replicating a similar, multifaceted approach to care for menopause could ensure a much smoother transition for women and their families during this critical reproductive life stage.<sup>36</sup> A "menopause preparedness" curriculum could incorporate quantitative and qualitative research and cultural perspectives to provide transparent and accessible information to women and their families in a way that establishes trust. It could also include complementary medical education and training for providers, especially those with a focus in midlife care. Effective menopause preparedness programming would promote pre-menopause wellness and, thus, improved health outcomes as individuals transition into postmenopausal life.<sup>37</sup>

Beyond the patient-provider relationship and personal support communities, intentional accommodation must be given to menopause across professional environments. The majority of women undergo the menopause transition while still in the workplace. Data suggest that menopause-associated reductions in productivity and job satisfaction may result in a broad negative economic impact.<sup>38</sup> The concept of menopauserelevant workplace policies has gained traction in countries such as Australia and the United Kingdom, where the Labour Party platform would mandate training and flexible leave policies for employers of large businesses.<sup>39</sup> Despite the differences in the national healthcare and workforce landscapes, US policymakers at the employer, state, and federal levels could use these countries' frameworks around workplace needs to drive similar domestic conversations and provide guidance for effective educational materials and policies in the United States.

## CONCLUSIONS

Menopause is often stigmatized and framed as if it were a disease, as opposed to a natural part of a woman's life cycle. A

holistic patient care model that emphasizes earlier and more robust education about the menopause transition for patients and providers would aid in the normalization of this life transition and improve quality of life for patients. Menopausal symptoms and experiences vary widely based on age of onset, overall patient health, and the specific type of menopause an individual experiences. All of these considerations should contribute to a personalized approach to care. Providers should consider which symptoms individuals are experiencing that hinder quality of life and what types of interventions—medical, lifestyle, and/or behavioral—are available to address them. A better understanding of these options and their potential outcomes requires a global increase in awareness and education among providers, patients, and even policymakers. Collecting data from diverse populations on the intersections of menopause and race, gender, culture, and socioeconomic status will better inform key stakeholders in the development of personalized care, innovative treatment options, and relevant policy solutions to improve the menopause experience for all individuals.

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