SA10

The Burden of Illness of Vasomotor Symptoms Associated with Menopause

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CONCLUSIONS

- **VMS associated with menopause incurs a substantial and under-reported burden in terms of clinical, humanistic and economic impact for women and health care systems, and the true impact may be higher**
- **VMS can be severe and have a detrimental impact on QoL and work/productivity**
- **VMS has a wider impact on women's relationships, families and careers**
- **There are limited effective treatment options, and a significant percentage of women are unable or unwilling to use available therapy**
- **There is an unmet need for increased choice in available effective treatment options for women with VMS associated with menopause**

OBJECTIVES

- The objective of this research was to comprehensively identify, assess and synthesize the available literature on the epidemiology, clinical burden, humanistic burden, economic burden and current treatment landscape of VMS associated with menopause, with a particular focus on data for the US

BACKGROUND

- The menopausal transition is characterized by the progressive decrease of estrogen levels due to loss of ovarian function.[1] Natural menopause, when monthly menstruation ceases due to a natural loss of ovarian follicular function, generally occurs in women between the ages of 45–55 years. It can last for up to 14 years[2, 3]
- By 2025, the number of postmenopausal women is expected to rise to 1.1 billion worldwide[4]
- Vasomotor symptoms (VMS; known as hot flushes) are the most common menopause symptoms and have a significant impact on affected women.[5] These symptoms start for many women in the perimenopausal phase, but they may continue throughout post-menopause[6]
- VMS is also one of the major menopause-related symptoms for which women seek medical treatment[7] and is associated with negative mood and sleep problems, resulting in a significantly poorer quality of life (QoL) during menopause[8]
- As a result, there are substantial health care and societal costs caused by VMS affecting everyday life and work productivity[9]

METHODS

- A targeted burden of illness (BOI) review was conducted including searches of MEDLINE®, Embase®, MEDLINE In-Process, Health Technology Assessment (HTA) Database and the National Health Service Economic Evaluation Database (NHS EED) to identify studies assessing the burden of VMS associated with menopause
  - The primary focus was US evidence, with evidence from additional countries included for evaluating humanistic burden (EU5 [France, Germany, Italy, Spain, UK], Nordics [Denmark, Finland, Iceland, Norway , Sweden], North America [US, Canada], Japan, China [including Hong Kong , Taiwan], South Korea ,Australia)
- The electronic database searches were supplemented with grey literature searches for regulatory approvals, HTA recommendations and clinical guidelines
- Existing literature reviews were also assessed for relevant evidence, including an economic systematic literature review (searches performed in January 2022) and a literature review on the epidemiology of menopausal symptoms (searches performed in April 2021)

RESULTS

- Of the 6,563 records identified from database searches and 51 from grey literature searches, 276 records were included in the final qualitative synthesis (101 of which were from existing reviews)

Epidemiology

Limited evidence is available on the actual number of women with VMS in the US – it is estimated at 40 million women (using prevalence estimates and 2020-2022 US Census Bureau data)

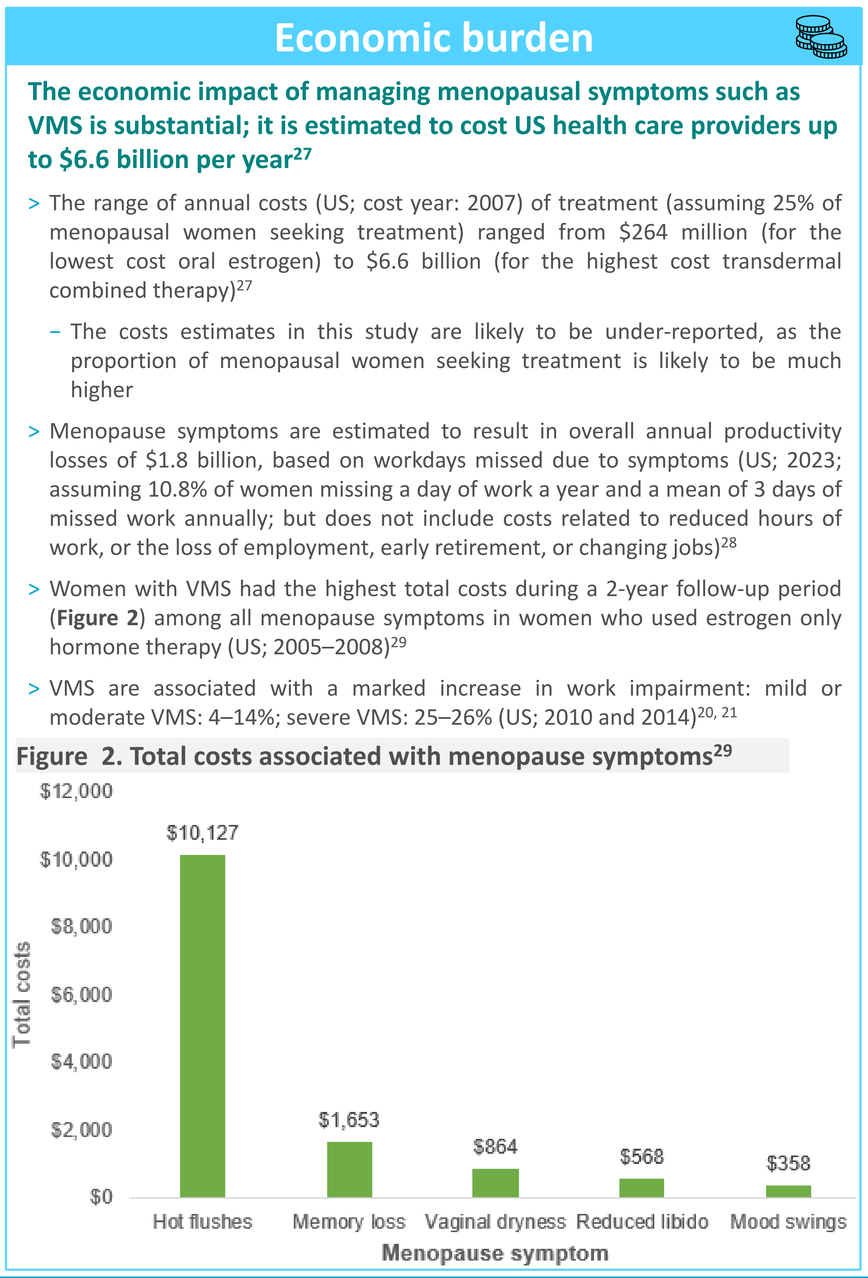
- Up to 80% of midlife women (45–52 years) reported experiencing VMS in the previous 2 weeks (SWAN study; US; 1996–2002)[10]
- The prevalence of moderate-to-severe hot flushes was reported to vary over the course of the menopausal transition (US; 1996–2012): peak of 46% in the first 2 years after the final menstrual period (FMP); decreased slowly after menopause until around 10 years after the FMP when it returned to premenopausal levels[11]
- The median total VMS duration was 7.4 years (US; 1996–2013); however, in some women VMS can occur for much longer[18]
- VMS associated with menopause disproportionally impacts certain racial and ethnic groups:
  - More common in African American/Black than in White menopausal women (US; 1995–2013),[10, 12-14] who also experience the longest duration of VMS (median: 10.1 years)[7]
  - Lower prevalence in Asian women compared with White women (US; 2004–2011)[15-17]

Economic burden

The economic impact of managing menopausal symptoms such as VMS is substantial; it is estimated to cost US health care providers up to $6.6 billion per year[27]

- The range of annual costs (US; cost year: 2007) of treatment (assuming 25% of menopausal women seeking treatment) ranged from $264 million (for the lowest cost oral estrogen) to $6.6 billion (for the highest cost transdermal combined therapy)[27]
  - The costs estimates in this study are likely to be under-reported, as the proportion of menopausal women seeking treatment is likely to be much higher
- Menopause symptoms are estimated to result in overall annual productivity losses of $1.8 billion, based on workdays missed due to symptoms (US; 2023; assuming 10.8% of women missing a day of work a year and a mean of 3 days of missed work annually; but does not include costs related to reduced hours of work, or the loss of employment, early retirement, or changing jobs)[28]
- Women with VMS had the highest total costs during a 2-year follow-up period (**Figure 2**) among all menopause symptoms in women who used estrogen only hormone therapy (US; 2005–2008)[29]
- VMS are associated with a marked increase in work impairment: mild or moderate VMS: 4–14%; severe VMS: 25–26% (US; 2010 and 2014)[20, 21]

Figure 2. Total costs associated with menopause symptoms[29]



Humanistic burden

VMS can negatively impact QoL by limiting women's ability to perform daily activities, productivity and impacting personal and social relationships

- The frequency of hot flushes varies; on average 4–5 hot flushes experienced per day, to as many as 20 per day (review published in 2018)[18]
- VMS has a substantial impact (rated moderate, severe, or "as bad as it can be"; UK, France, Germany, Italy, Spain and the US; 2020) on:[19]
  - Sleep (35.8% of menopausal women with VMS)
  - Mood (31.6% of menopausal women with VMS)
  - QoL (23.6% of menopausal women with VMS)
  - Work/study (15.4% of menopausal women with VMS)
- VMS impact various aspects of women's lives, including their ability to work and perform daily activities (US; 2010 and 2014).[20, 21]
- Women experiencing severe VMS reported activity impairment almost twice that of women with mild/moderate VMS (34.0% versus 17.4%, respectively; $p < 0.001$) and higher overall work impairment (25.7% vs 14.3%; $p = 0.028$)[21]

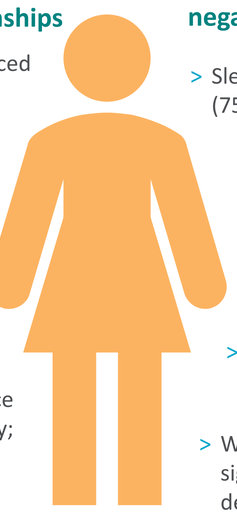
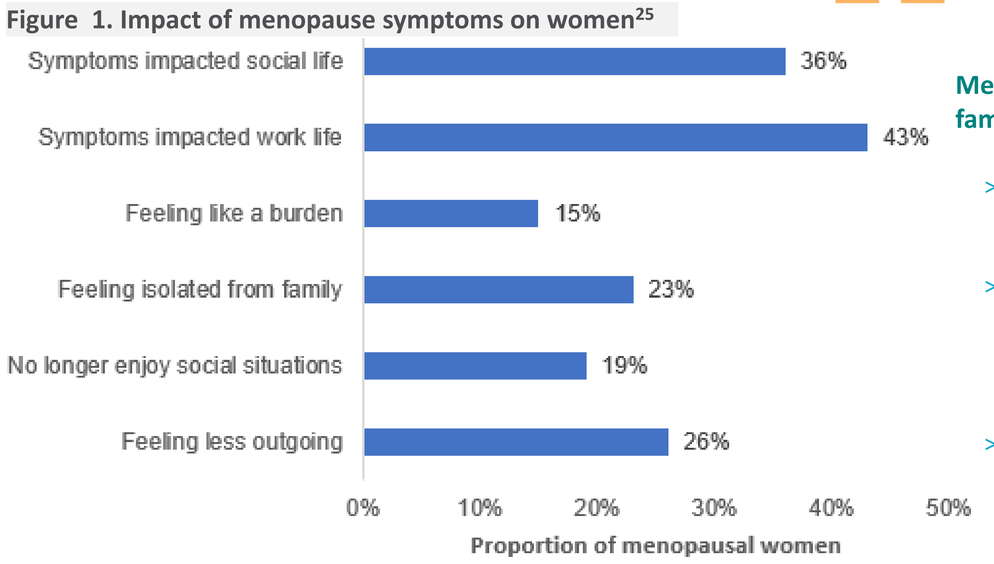


Figure 1. Impact of menopause symptoms on women[25]



Note: Of the women surveyed, 79% and 70% were experiencing or had experienced hot flushes or night sweats, respectively.

VMS related sleep disturbances and mood changes negatively impact overall health and QoL

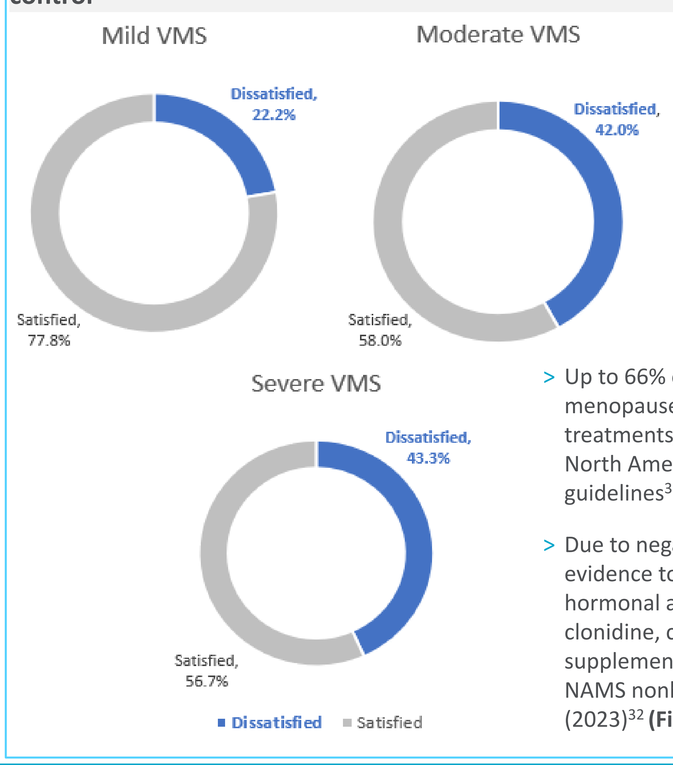
- Sleep disturbance was the most bothersome aspect of VMS (75% in the US; 50% in the EU)[22]
  - In a study published in 2020, most women with VMS (US: 93.8%; EU: 93.8%) had their sleep affected by VMS; specifically, they had sleep interrupted by physical discomfort (e.g., sweating and overheating) and experienced difficulties returning to sleep.[22]
- The risk of depressive symptoms was significantly higher in women with hot flushes (US; 1996–2010; $p = 0.001$)[23]
- Women with menopausal symptoms and depression had significantly impaired QoL compared with women without depression (US; 2005)[24]

Menopause also impacts relationships with partners, families and careers

- Approximately half of women aged ≥ 45 years with menopausal symptoms reported that menopause impacted their home life (**Figure 1**; UK survey; 2017)[25]
- Menopause can also cause difficulties in personal relationships: 22% of women and 28% of partners reported that since the start of menopause, they often had arguments because of their partner's lack of understanding of menopause[25]
- Of all menopausal symptoms, more than 40% of women reported hot flushes are the most difficult symptom to deal with at work (US; 2022)[26]

Current treatments

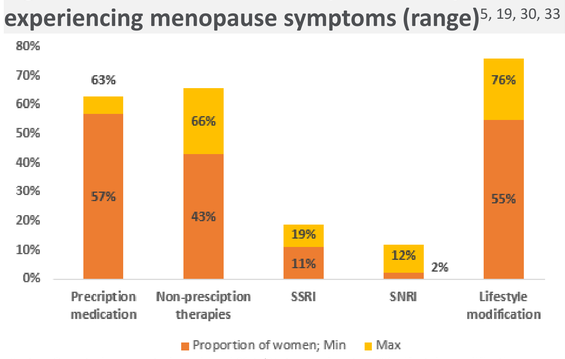
Figure 3. Patient-reported satisfaction with level of VMS control[19]



Women experiencing VMS need increased choice in safe and effective treatment options – especially women who want treatment, but who are not willing or able to use current therapies

- In US clinical practice, 66–70% of menopausal women are prescribed hormone therapy to treat VMS[19, 30]
- Hormone therapy is not suitable for all women due to long-term use risks, contraindications or patient preference[31]
  - 53–68% of women eligible for hormone therapy don't use it[5, 19]
- Approximately one-third of women (US and EU; 2020) reported dissatisfaction with their VMS control; those with more severe VMS were more commonly dissatisfied (**Figure 3**)[19]
- Up to 66% of women experiencing menopause symptoms use non-prescription treatments, which are not recommended by North American Menopause Society (NAMS) guidelines[32] **(Figure 4)**
- Due to negative, insufficient or inconclusive evidence to support efficacy, also many non-hormonal alternatives (e.g., pregabalin, clonidine, cooling techniques, and dietary supplements) are not recommended by NAMS nonhormone therapy guidelines (2023)[32] **(Figure 4)**

Figure 4. Non-hormone therapies used by women experiencing menopause symptoms (range)[5, 19, 30, 33]



Notes: One study presented combined SSRI/SNRI use of up to 40%. Lifestyle modifications include keeping cool, rest and relaxation, wearing loose clothing and increased level of exercise. Non-prescription therapies include herbal remedies, such as black cohosh, and CBT.

Disclosures

Jean Malacan was an employee of Bayer Consumer Carer AG, Basel, Switzerland at the time of producing this poster. Kristina Bolling is an employee of Bayer U.S. LLC, Whippany, NJ, USA. Claudia Haberland is an employee of Bayer AG, Berlin, Germany. Lucian Gaianu was an employee of Bayer Public Limited Company, Reading, UK at the time of producing this poster. Nicola Smith, Matthew Woods, and Michelle Smith are employees of Lumanity, UK.

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References

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