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Examining the Value of Menopausal Symptom Relief Among US Women

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ABSTRACT

Background: Menopausal symptoms can cause significant distress to women, yet little is known about the value women place on these symptoms. **Methods:** In April 2013, 3397 US women, aged 40 to 69 years, completed an online survey that included 30 paired comparisons. Specifically, respondents were shown two menopausal symptoms described using the Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events and asked, “Which do you prefer?” From their choices, we estimated a generalized linear model to assess the values women place on symptom relief in terms of quality-adjusted life-years (QALYs). **Results:** Approximately half the respondents (1753 of 3397 [52%]) always preferred a reduced lifespan (up to 90 days) instead of experiencing menopausal symptoms at their worst for 30 days. For most of the symptoms (248 of 263 [94%]), including low-grade events, QALYs were significantly reduced ($P < 0.05$). The value women placed on relief ranged widely by symptom domain: the relief from depression, problems with memory, headache, pain in abdomen, problems with anger, and vomiting were

the most valuable. **Conclusions:** Overall, the value women place on menopausal symptom relief is surprisingly high. As the first national study to directly ask women about their preferences and to estimate the value of menopausal symptom relief on a QALY scale, this work provides critical evidence for health outcomes research in midlife women and can be applied in the evaluation of treatments that reduce or eliminate menopausal symptoms. This work also provides proof-of-concept for an approach to value Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events responses on a QALY scale.

Keywords: menopause, Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE), preference, QALY, quality-adjusted life-year, symptoms, women’s health.

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Introduction

Menopause reflects not only the cessation of reproductive capacity but also often includes a multitude of associated symptoms that can negatively affect women’s health-related quality of life [1,2]. Whether part of the natural aging process, an adverse effect of medical treatment, or damage to the ovaries, the symptoms that accompany menopause can be measured using one of the available patient-reported outcome (PRO) instruments (Table 1) [3–12]. No study, however, has asked women which symptoms and symptom attributes (frequency, severity, and interference) matter most to them. Understanding what women experience and what they value in terms of symptoms is critical for women’s health care, including the evaluation of new health technologies (e.g., Duavee), the assessment of treatment regimens (e.g., chemotherapy), and other forms of comparative effectiveness research.

The National Cancer Institute’s PRO version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) measurement system allows patients to self-report symptomatic adverse

events (AEs) [13–15]. This system is intended to complement National Cancer Institute’s CTCAE, an existing lexicon of clinician-reported AE items required for use in all National Cancer Institute-sponsored trials. The PRO-CTCAE item library is composed of 126 items that evaluate the presence, frequency, severity, and interference with usual or daily activities associated with 78 symptomatic toxicities [16–18]. Given PRO-CTCAE’s focus on self-reported AEs relating to treatment, it was particularly well suited for the creation of the MP-30D, a PRO checklist for the measurement of symptoms related to menopause. The primary focus of this article was a health valuation study of the MP-30D from the perspective of US women aged 40 to 69 years.

Health valuation studies are commonplace throughout the clinical literature; yet to our knowledge, this is the first study that asked women about their preferences regarding symptoms associated with menopause [19–23]. Nearly all past studies focused on gender-neutral PRO instruments (e.g., the EuroQol five-dimensional questionnaire), most taking the societal perspective [24–27]. This reliance on gender-neutral domains (i.e., those

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Table 1 – MP-30D domains: Comparison to HRQOL instruments for menopause.

MP-30D domains arranged by the CTCAE system organ class ^a	HRQOL instruments for menopause								
	BESS [4]	MENCAV [3]	MENQOL [8]	WHQ [46]	WHQ-R [7]	MRS [11]	UQOL [11]	MQOL [10]	Greene [47]
Cardiac disorders									
1. Pounding or racing heartbeat: F, S	X	X		X	X	X			X
Gastrointestinal disorders									
2. Pain in the abdomen: F, S, I				X					
3. Constipation: S	X								
4. Increased passing of gas: P			X						
5. Nausea: F, S	X			X	X				
6. Vomiting: F, S	X								
7. Bloating of the abdomen: F, S			X	X	X				
Metabolism and nutrition disorders									
8. Decreased appetite: S, I	X			X	X		X	X	
Musculoskeletal and connective tissue disorders									
9. Aching joints; aching muscles; back pain: F, S, I	X	X	X		X	X			X
Psychiatric disorders									
10. Insomnia: S, I	X	X	X	X	X	X			X
11. Anxiety: F, S, I		X	X	X	X	X	X	X	X
12. Depression [†] : F, S, I		X	X	X	X	X	X	X	X
13. Irritability: F, S, I	X	X	X	X		X		X	X
14. Problems with anger: F, S, I								X	
15. Decreased sexual interest: S		X	X	X	X	X		X	X
Renal and urinary disorders									
16. Urinary problems [‡] : F, I	X		X	X		X			
17. Pain or burning with urination: S		X							
Nervous system disorders									
18. Numbness or tingling in your hands or feet: S, I	X	X		X					X
19. Dizziness: S, I	X	X		X	X				X
20. Headache: F, S, I	X	X	X	X	X				X
21. Problems with memory: S, I	X		X	X	X			X	
22. Problems with concentration: S, I	X	X	X	X	X			X	X
Reproductive system and breast disorders									
23. Irregular menstrual periods: P	X		X						
24. Vaginal dryness: S	X		X			X			
25. Pain during vaginal sex: S	X		X	X	X		X	X	
26. Breast area enlargement or tenderness: S	X		X	X	X				
Skin and subcutaneous tissue disorders									
27. Unexpected or excessive sweating: F, S	X	X	X	X	X			X	X
28. Dry skin; Itchy skin: S			X						
Vascular disorders									
29. Hot flashes: F, S	X		X	X	X	X		X	X
General disorders									
30. Fatigue, tiredness, or lack of energy: S, I		X	X	X	X	X		X	X

BESS, Breast Cancer Prevention Trial Eight Symptom Scale; HRQOL, health-related quality of life; MENCAV, Calidad de Vida en Menopausia (Quality of life during menopause); MENQOL, Menopause-Specific Quality of Life; MQOL, Menopausal Quality of Life Scale; MRS, Menopause Rating Scale; PRO-CTCAE, Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events; UQOL, Utian Menopause Quality-of-Life Score; WHQ, Women's Health Questionnaire; WHQ-R, Women's Health Questionnaire-Revised.

* The MP-30D includes 30 checkboxes (1 for each domain) and 72 five-level items describing symptom frequency (F), severity (S), and interference (I) with usual activities. Among 72 F, S, and I items (listed above), 63 originated from the PRO-CTCAE v1.0; however, the F, S, and I items for back pain, irritability, and problems with anger did not because these symptoms are not in the PRO-CTCAE v1.0.

[†] Depression includes two symptoms (Feeling that nothing could cheer you up; Sad or unhappy feelings), and Urinary problems includes three symptoms (Frequent urination; Urges to urinate all of the sudden; Loss of control of urine).

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