JOURNAL OF WOMEN'S HEALTH
Volume 17, Number 3, 2008

DOI: 10.1089/jwh.2007.0377

Development and Validation of the Premenstrual Symptoms Impact Survey (PMSIS): A Disease-Specific Quality of Life Assessment Tool

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ABSTRACT

***Objective*: To develop and validate the Premenstrual Symptoms Impact Survey (PMSIS), a brief web-based instrument for evaluating the impact of premenstrual symptoms on health-related quality of life (HRQOL).**

***Methods*: An item bank of 68 questions was administered to a nationally representative sample of 971 women using the web, aged 18–45, who experienced regular menstrual cycles in the past 3 months, were not currently pregnant or breastfeeding, and were not being treated or taking medications for depression-related disorders in the last 2 years. Item reduction was performed using forward stepwise linear regression of an overall symptom severity score onto item scores. Three standards were used to validate the instrument: (1) the American College of Obstetricians and Gynecologists retrospective diagnostic criteria for identifying participants "at risk" for clinically significant premenstrual syndrome (PMS), (2) the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders* retrospective diagnostic criteria for identifying participants at risk for premenstrual dysphoric disorder (PMDD), and (3) the Medical Outcomes Study Short Form (SF-12) Health Survey.**

***Results*: Six items met entry criteria in the model. Approximately 6.0% of the participants were identified as being at risk for PMDD, and 17.3% were identified as being at risk for clinically significant PMS. PMSIS scale score differed significantly between participants who were and were not at risk for PMDD/clinically significant PMS. PMSIS scale score also differed significantly between participants having either high, average, or low HRQOL as defined by SF-12 physical and mental component summary scores.**

***Conclusions*: These results demonstrate that the PMSIS has excellent discriminative ability to detect differences in groups that are known to differ in terms of clinical criteria. The PMSIS can be used to educate consumers about the impact of their symptoms on QOL.**

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INTRODUCTION

Premenstrual symptoms are common in women of reproductive age, typically recurring 5–7 days before the onset of menstruation and attenuating when the menstrual period begins or shortly thereafter.[1] The constellation of symptoms may include affective symptoms, such as depression, irritability, anxiety, confusion, and social withdrawal, as well as somatic symptoms, such as breast tenderness, abdominal bloating, headache, and swelling of extremities.[2] About 80% of reproductive age women experience some symptoms prior to their menstrual cycle,[3] and between 12.6% and 31.0% of women report clinically significant premenstrual symptoms or premenstrual syndrome (PMS).[1,4–8]

Premenstrual dysphoric disorder (PMDD) is a severe form of PMS that includes the presence of at least five of the following physical, emotional, and behavioral symptoms: (1) markedly depressed mood, feelings of hopelessness, or self-deprecating thoughts, (2) marked anxiety and tension, 3) marked affective liability, (4) irritability, (5) decreased interest in usual activities, (6) difficulty in concentrating, (7) marked lack of energy, (8) marked change in appetite or cravings, (9) insomnia or hypersomnia, (10) feeling overwhelmed, and (11) physical symptoms, such as breast tenderness or swelling, headaches, joint or muscle pain, and bloating.[2] It is widely reported that between 3% and 8% of women of reproductive age meet strict criteria for PMDD, and about 13% to 18% of women experience some symptoms of PMDD that are severe enough to warrant treatment but do not meet the count of five symptoms as listed in the DSM-IV-TR criteria.[1,3,4,6,7]

The burden of PMDD on health-related quality of life (HRQOL) has been compared with that of dysthymic disorder and major depressive disorder (MDD), particularly in terms of its impact on social and work functioning.[8,9] This impact on HRQOL translates into significant deficits in work productivity and marked economic burden.[10] A recent study reported the annual indirect costs of PMS (quantified by self-reported days of missed work and lost productivity at work) to be approximately $6877 per patient.[11] Annual direct health plan costs for 10,000 women with PMS with an age range of 18–45 years and a mean age of 34.5 years were estimated to be $174,936, and the annual indirect costs for the same patient population were estimated to be $12,795,535.[11]

Given the high prevalence of premenstrual symptoms and their significant economic and HRQOL burden, an important public health challenge has been to provide women with a brief, self-assessment tool for measuring the impact of these symptoms on their daily functioning and HRQOL. Although there are many instruments that document the presence and severity of premenstrual symptoms (both retrospective questionnaires and prospective/concurrent daily checklists), there is a need for a psychometrically valid and reliable instrument that evaluates the impact of such symptoms on HRQOL. The goal in developing the Premenstrual Symptoms Impact Survey (PMSIS) has been to identify the HRQOL domains that are most affected by premenstrual symptoms and construct a brief, web-based instrument to measure this impact and provide norm-based feedback (e.g., the individual's score relative to the general population mean). Such feedback can educate consumers and be shared with their medical providers, thus encouraging patient-provider dialogue.

MATERIALS AND METHODS

Item development and survey questions

The primary HRQOL domains that are impacted by premenstrual symptoms were identified through a comprehensive literature review and in consultation with a clinical work group composed of three leading specialists in obstetrics/gynecology and one general practice physician. Sixty-eight items were developed for testing based on the literature review and clinical group consult.

In addition to the item bank for the PMSIS, subjects were asked to provide information about demographics, general medical history, reproductive history, employment and productivity, the presence and severity of premenstrual symptoms over their last three menstrual cycles, and their HRQOL over the last 4 weeks using the Medical Outcomes Study Short Form (SF-12) Health Survey.[12] Premenstrual symptom severity was evaluated using the following language: "This survey refers to premenstrual symptoms that occur 5–7 days before the onset of your menstrual period and go away when your menstrual period begins or shortly thereafter. Please indicate which premenstrual symptoms have been present during

the majority of your last three cycles." Symptom severity was coded on a 6-point Likert scale (No symptom = 0, Very mild = 1, Mild = 2, Moderate = 3, Severe = 4, Very severe = 5). A list of 20 premenstrual symptoms was derived from the literature review, consultation with the clinical group, and examination of existing premenstrual symptom checklists including the Daily Record of Severity of Problems (DRSP), the Daily Symptom Report, and the Menstrual Distress Questionnaire (MDQ).[13–15] An overall symptom severity score was calculated by summing the responses across each possible symptom, yielding a range of 0 (no symptoms) to 100 (Very severe response on all symptoms). The SF-12 evaluates HRQOL across eight primary domains that include Physical Functioning, Bodily Pain, Role Physical, General Health, Vitality, Social Functioning, Role Emotional, and Mental Health. These domains can be further aggregated into two summary scores for physical (Physical Component Summary [PCS]) and mental (Mental Component Summary [MCS]) health.[12]

Data collection

As the intent was to create a web-based instrument, the draft items and additional survey questions were administered to a general U.S. population sample in a cross-sectional study over the Internet via a trusted partner, secure website (Zoomerang Inc.). Zoomerang is an online survey company that maintains a nationwide panel of members who are interested in completing surveys. In return, panelists earn points, which are redeemable for a variety of merchandise (e.g., books, magazine subscriptions, CDs, DVDs, electronics). Participants were randomly selected from the ZoomPanel database and invited to participate in the study through an e-mail invitation.

Study participants

The draft survey items were administered to a nationwide sample of women aged 18–45 during a 1-week period in August 2005. A total of 1637 ZoomPanel members accepted the invitation to participate in the study. To qualify for inclusion, participants had to meet the following criteria: (1) female, (2) age 18–45, (3) fluent in English, (4) not currently pregnant or breastfeeding, (5) must have experienced regular menstrual cycles for the past 3 months (i.e., menstrual periods occurring every 24–36 days), (6) have not used antidepressants, antianxiety medication, or hormone replacement therapy (HRT) during the last 3 months, and (7) have not received professional treatment for depression (MDD), anxiety (panic, obsessive-compulsive, posttraumatic stress), eating disorders, or drug or alcohol problems during the last 2 years.

Item selection of the PMSIS

Item selection and development of the PMSIS were based on choosing a random sample of 500 participants from the total working sample (n = 971). Reasoning that symptom severity is expected to correlate with the impact of symptoms on HRQOL, the primary developmental criterion for item selection was self-reported premenstrual symptom severity using the 20-item symptom list (yielding the Symptom Severity Score). Stepwise linear regression methods were used to identify survey items with the greatest ability to discriminate among differing levels of symptom severity. Items were entered into the model in a forward stepwise fashion. The criterion for entry was discrimination at a statistical significance level of $p < 0.05$. All 68 draft items were entered as independent variables in the stepwise regression model. The dependent variable was overall Symptom Severity Score (continuous sum score between 0 and 100). Items meeting entry criteria ($p < 0.05$) were selected for inclusion in the final short-form PMSIS.

Reliability

Determination of all psychometric properties, including scale structure, reliability, and validity, was conducted on the remaining 471 holdout sample of the total working sample (n = 971). After the final PMSIS items were identified from the regression analyses, reliability was evaluated by calculating Cronbach's alpha[16] as a measure of internal consistency reliability.

Assessment of scale structure and unidimensionality

Scale structure was evaluated by conducting a principal components analysis with varimax rotation. This was followed by confirmatory factor analysis and assessment of model fit (nonsignificant chi-square and root mean square error of approximation [RMSEA] < 0.06).[17] Tests for multi-

variate normality were conducted prior to factor extraction. Unidimensionality was assessed by examining the ratio of the first and remaining eigenvalues in accounting for the covariance of item responses.

Empirical validation in relation to HRQOL

Once the final subset of items comprising the PMSIS was identified, a PMSIS score value was derived by simply summing across all item responses and then transforming that value to a 0 (no impact on HRQOL) to 100 (highest possible impact) scale. Tests of validity were designed to address issues that are related to the intended use of the instrument. Because the PMSIS was constructed to evaluate the impact of premenstrual symptoms on HRQOL, the instrument should discriminate between groups known to differ along quality of life dimensions. This method of construct validation is referred to as known-groups validity.[18]

First, Pearson correlations were calculated between PMSIS score and SF-12 domain and summary scores to determine if significant relationships existed between the variables. Second, participants were categorized into three groups based on the 95% confidence interval (95% CI) of the SF-12 summary score distributions: a low HRQOL group of participants who scored lower than 2 standard error of measurement (SEM) units below the mean MCS score, a middle group of participants who scored between 2 SEM units below and 2 SEM units above the mean MCS score, and a high group who scored higher than 2 SEM units above the mean MCS score. A similar three-group categorization was performed using PCS scores. Previous studies have shown that differences of this magnitude in PCS and MCS scores have been linked to significant differences in a number of important functional (e.g., employment, productivity) and clinical (e.g., hospitalization risk, mortality) outcomes.[13]

Tests of homogeneity (Levene) were conducted prior to running a univariate analysis of variance (ANOVA) that tested for differences in PMSIS mean score as a function of HRQOL group participation. Adjustment for multiple comparisons was included using a conservative Bonferroni correction. Our hypothesis was that higher PMSIS scores (indicating greater impact of HRQOL) would be observed in the low HRQOL groups, whereas lower PMSIS scores would be observed for the high HRQOL groups.

Empirical validation in relation to diagnostic criteria

Another intended use of the PMSIS is to provide norm-based feedback to women about the impact of premenstrual symptoms on their HRQOL relative to groups of women who may be at risk for clinically significant PMS or PMDD. In order to identify participants in our study who might be at risk for either clinically significant PMS or PMDD, we operationalized the commonly accepted gold standards for these conditions and included these questions with those addressing medical reproductive history.

The retrospective component of the American College of Obstetricians and Gynecologists (ACOG) diagnostic criteria for premenstrual syndrome was used to identify participants at risk for clinically significant PMS.[19] The ACOG criteria require reporting at least one core affective or somatic symptom during the 5 days before menses that is relieved within 4 days of the onset of menses. Of key importance, the ACOG criteria also state that the symptom(s) must be associated with impairment or dysfunction in social or economic performance. The retrospective component of the DSM-IV-TR diagnostic criteria for PMDD was used to identify participants at risk for PMDD.[2] The diagnosis of PMDD is based on the presence of a specific symptom set and associated impairment or dysfunction over the past year.

Dichotomous groups were derived based on being at risk for clinically significant PMS (yes or no) and PMDD (yes or no). Univariate ANOVAs were conducted to test for differences in PMSIS mean score as a function of group participation. Adjustments for multiple comparisons were addressed using a conservative Bonferroni correction. Our hypothesis was that higher PMSIS scores would be observed in the groups at risk for clinically significant PMS and PMDD compared with those who were not part of this group.

Receiver operating characteristic (ROC) analyses were conducted to assess the ability of the PMSIS to detect women at risk for clinically significant PMS and PMDD. Sensitivity and specificity were estimated for each threshold value of the PMSIS.

RESULTS

Sample characteristics

Of the 1637 women who were invited to participate, a total of 971 women met our inclusion criteria. Of these 971 women, 86.5% were Caucasian, 4.9% were African American, 3.0% were Asian American, and the rest was divided equally among Pacific Islanders, American Indians, or declined to answer. About 5.6% of the sample reported their ethnicity as Hispanic. The average age of the respondents was 31.4 years (SD 7.3 years), with a range of 18–45 years.

Two groups of women were identified based on our diagnostic criteria questions. The first group consisted of 6.0% of our sample who met the retrospective component of the DSM-IV-TR criteria for PMDD.[2] In this group, women reported at least one of the four core symptoms (tension, lability of mood, dysphoria, or irritability) as "severe" or "very severe" and at least four additional symptoms as "moderate" to "very severe." Additionally, they had to report that these symptoms markedly interfered with their ability to function in at least one of five domains (work/productivity, home responsibilities, social life, relationships at home, or relationships at work). This group was identified as "at risk for PMDD."

A second group was identified (17.3%) who did not reach PMDD risk criteria but reported at least one of the core symptoms as "moderate" to "very severe" and at least four additional symptoms as "moderate" to "very severe." They also reported that these symptoms markedly interfered with their ability to function in at least one of the five life domains. This group was identified as "at risk for clinically significant PMS."[3]

Item selection

As shown in Table 1, the forward stepwise regression resulted in six items satisfying the model inclusion criteria. Overall model fit was statistically significant ($F = 239.9$, $p < 0.0001$, adjusted $R^2 = 0.65$). Because all items are calibrated to the same metric, the unstandardized regression coefficients can be used to evaluate the relative strength of association between each item and the total symptom severity score. The first item selected into the model (largest regression term) concerned the impact of premenstrual symptoms on mood. This item was followed by "symptoms left you too tired to work," "felt frustrated because of symptoms," "symptoms limited ability to concentrate," "got tense because of symptoms," and "symptoms kept you from socializing" (see Appendix for complete items). These six items comprise the PMSIS.

Reliability

The internal consistency reliability of the six-item PMSIS was 0.90 in the holdout sample ($n = 471$). Among the 28 people (6%) who were categorized as being at risk for PMDD, the internal consistency reliability was 0.89. For those categorized as being at risk for clinically significant PMS ($n = 81$), the internal consistency reliability was 0.89.

Assessment of scale structure and unidimensionality

A principal components analysis (with varimax rotation) of the six items that comprise the PMSIS was performed on the holdout sample and resulted in the first factor accounting for approximately 67.1% of the total variation in the data ($\lambda_1 = 4.02$). The factor loadings ranged from 0.79

Table 1. Results of Forward Selection of PMSIS Items Using Stepwise Regression

	Unstandardized coefficients				*95% CI for β*	
Item description	*β*	*Standard error*	t	p	*Lower boundary*	*Upper boundary*
PMSIS1—Felt frustrated because of symptoms	2.690	0.631	4.261	<0.0001	1.450	3.929
PMSIS2—Mood swings because of symptoms	4.704	0.532	8.842	<0.0001	3.659	5.748
PMSIS3—Symptoms limited ability to concentrate	2.578	0.707	3.647	<0.0001	1.190	3.965
PMSIS4—Got tense because of symptoms	2.304	0.627	3.677	<0.0001	1.074	3.534
PMSIS5—Symptoms left you too tired to work	4.529	0.638	7.094	<0.0001	3.276	5.782
PMSIS6—Symptoms kept you from socializing	1.283	0.651	1.971	0.049	0.005	2.562

to 0.86. Confirmatory factor analysis of a single factor model showed adequate model fit suggesting unidimensionality (chi-square = 7.65, $p > 0.2$, RMSEA = 0.055).

Scoring the PMSIS distribution

As all selected items for the PMSIS scale in the same direction and share a common metric, total score was calculated by simply summing across all six items. Each response had an impact severity range of 1 (no impact) to 5 (high impact), resulting in a total score range of 6 to 30. To simplify interpretation, this scale score was then translated to a 0 (no impact) to 100 (highest impact) range. In Figure 1, we show the distribution to PMSIS scale scores for the holdout sample. The mean of the sample was 26.6 (SD 22.1). No violations of normality were observed (standardized skewness [Z] = 0.079, $p > 0.05$)

Empirical validation in relation to HRQOL

Pearson correlations between the PMSIS scale score and the SF-12 domains were all significant ($p < 0.01$) and ranged from −0.52 (Social Functioning) to −0.22 (General Health).

A univariate ANOVA was conducted to test for differences in PMSIS scale score as a function of belonging to the low, middle, or high SF-12 PCS group. A Levene test for the homogeneity of variance across the group was not statistically significant. The univariate ANOVA showed that PMSIS scale scores differed significantly as a function of group participation ($F = 6.4$, $p < 0.002$, partial $\eta^2 = 0.3$). *Post hoc* comparisons of the marginal means (Bonferroni) revealed significant differences in PMSIS scale score between those in the PCS low and middle groups ($p < 0.01$) and between the low and high groups ($p < 0.05$).

A univariate ANOVA was conducted to test for differences in PMSIS scale score as a function of belonging to the low, middle, or high SF-12 MCS group. A Levene test for the homogeneity of variance across the group was not statistically significant. The univariate ANOVA showed that PMSIS scale scores differed significantly as a function of group participation ($F = 21.1$, $p < 0.0001$, partial $\eta^2 = 0.9$). *Post hoc* comparisons of the mar-

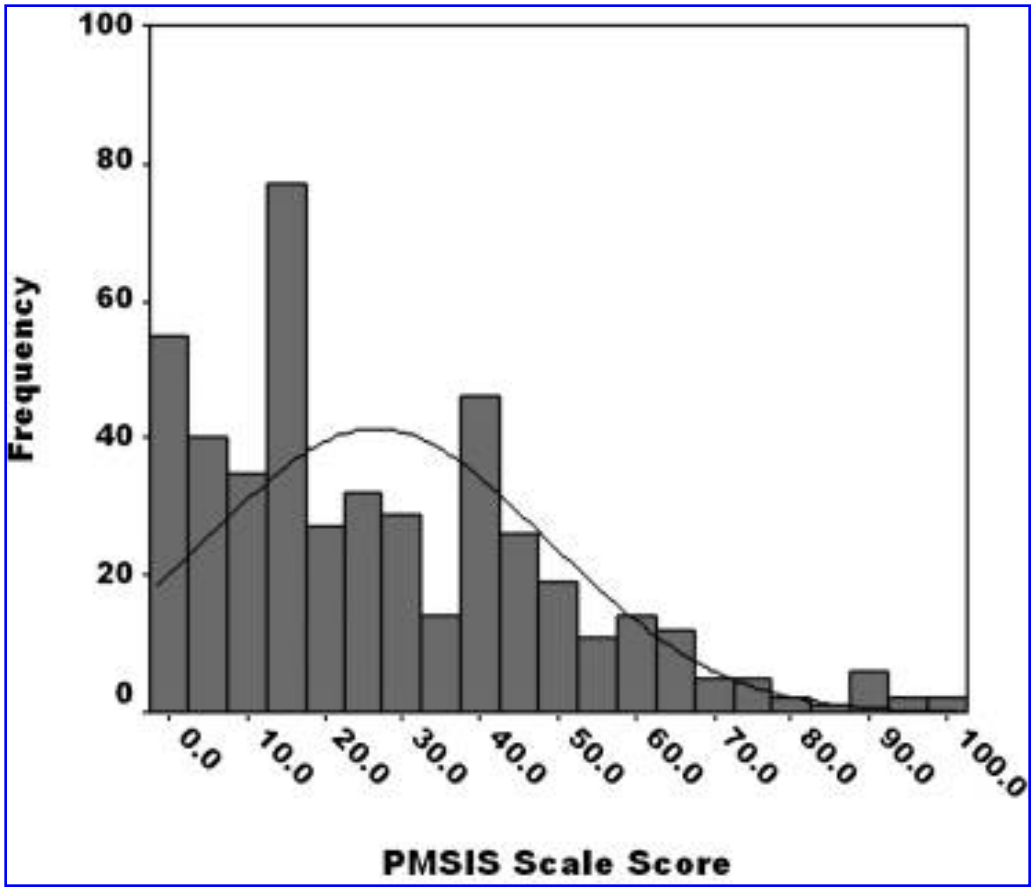

FIG. 1. Distribution of PMSIS scale scores with a fitted normal curve.

ginal means (Bonferroni) revealed significant differences in PMSIS scale score between those in the MCS low and middle groups ($p < 0.001$) and between the low and high groups ($p < 0.001$). Marginal means and SDs are presented in Table 2.

Empirical validation in relation to diagnostic criteria

A univariate ANOVA was conducted to test for differences in PMSIS scale score as a function of being at risk for PMDD. A Levene test for the homogeneity of variance across the group was not statistically significant. The univariate ANOVA showed that PMSIS scale scores were significantly higher for the at risk for PMDD group (μ = 63.1, SD 21.3) when compared with the group of participants not at risk (μ = 25.9, SD 19.7) (F = 95.3, $p < 0.0001$, partial $\eta^2 = 0.17$).

A univariate ANOVA was conducted to test for differences in PMSIS scale score as a function of being at risk for clinically significant PMS. A Levene test for the homogeneity of variance across the group was not statistically significant. The univariate ANOVA showed that PMSIS scale scores were significantly higher for the at risk for clinically significant PMS group (μ = 52.6, SD 20.2) when compared with the group of participants not at risk (μ = 22.3, SD 17.7) (F = 199.3, $p < 0.0001$, partial $\eta^2 = 0.3$).

Figures 2A and 2B show the ROC curves associated with detecting participants at risk for PMDD and clinically significant PMS, respectively, using PMSIS scale scores. The area under the curve (AUC) was 0.90 for detecting participants at risk for PMDD ($p < 0.0001$) and 0.92 for detecting participants at risk for clinically significant PMS ($p < 0.0001$). Both values were significantly greater than chance (AUC = 0.50). In Table 3, we show the sensitivity and specificity for the PMSIS in detecting these states using different thresholds. Sensitivity is the proportion of true positive tests per total number of subjects affected by a condition (in this case, those identified to be at risk for clinically significant PMS or PMDD). Contrasting this, specificity is the proportion of true negative tests per total number of subjects unaffected by the condition.

DISCUSSION

At present, there are many instruments available to evaluate and screen for the presence of symptoms related to the menstrual cycle.[20–22] In general, they fall into two broad categories, those that use retrospective reporting of symptoms based on memory and others that use prospective/concurrent reporting based on daily symptom checklists. Retrospective screening tools have been criticized for their reliance on memory,[20] and prospective charting suffers from the increased burden placed on patients and the resulting sample bias that can occur with high levels of nonadherence.[21]

Although many instruments exist that document the presence and severity of premenstrual symptoms, there is current need for a psychometrically valid and reliable instrument that evaluates the impact of such symptoms on HRQOL. The goal in developing the PMSIS has been to first identify the major HRQOL domains that are affected by premenstrual symptoms and then construct a psychometrically sound, brief instrument to measure this impact and provide norm-based feedback to women. Consistent with this goal, we adopted validation criteria from commonly accepted gold standards in both the HRQOL (SF-12 summary measures) and clinical literature (DSM-IV-TR and ACOG diagnostic criteria for PMDD and clinically significant PMS).

The PMSIS consists of six items that tap into several HRQOL domains, including mental health, social functioning, vitality, and role functioning. The derivation of the PMSIS was done by regressing all potential items onto the overall Symptom Severity Score; hence, a high degree of correlation exists between the two scores. Using a holdout sample, we found the PMSIS has ex-

Table 2. Mean (SD) PMSIS Scale Scores for Different Group Criteria

Score distribution	*Physical component summary (PCS)*	*Mental component summary (MCS)*
Low	41.4 (23.8)	51.1 (22.8)
Middle	27.3 (21.5)	27.4 (21.0)
High	27.7 (21.8)	12.5 (13.6)

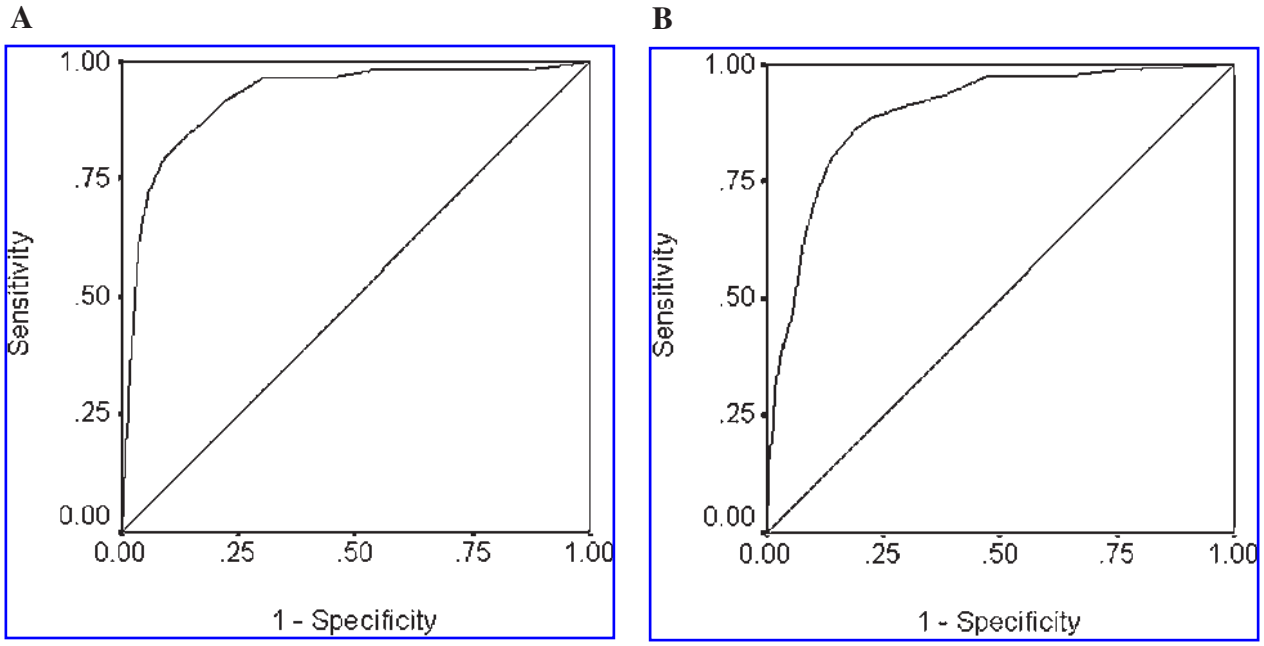

FIG. 2. ROC curve analysis using PMSIS scale score to identify (**A**) participants at risk for PMDD and (**B**) participants at risk for clinically significant PMS.

TABLE 3. SENSITIVITY AND SPECIFICITY OF PMSIS

	PMDD		*Clinically significant PMS*	
Threshold	*Sensitivity*	*Specificity*	*Sensitivity*	*Specificity*
0	1.00	0.00	1.00	0.00
2	0.98	0.13	0.99	0.13
6	0.98	0.21	0.99	0.21
10	0.98	0.30	0.98	0.30
15	0.98	0.39	0.98	0.39
19	0.98	0.46	0.98	0.46
23	0.96	0.55	0.93	0.55
27	0.96	0.63	0.91	0.63
31	0.96	0.70	0.89	0.70
35	0.95	0.73	0.86	0.73
40	0.91	0.79	0.80	0.79
44	0.88	0.82	0.73	0.82
48	0.84	0.87	0.63	0.87
51	0.79	0.91	0.47	0.91
56	0.72	0.95	0.38	0.95
60	0.61	0.97	0.30	0.97
65	0.46	0.97	0.23	0.97
69	0.35	0.98	0.17	0.98
73	0.30	0.99	0.14	0.99
77	0.21	0.99	0.10	0.99
81	0.19	0.99	0.09	0.99
85	0.14	0.99	0.07	0.99
90	0.11	1.00	0.05	1.00
94	0.07	1.00	0.04	1.00
98	0.02	1.00	0.01	1.00
100	0.00	1.00	0.00	1.00

cellent internal consistency reliability for the overall sample and a number of subgroups.

By comparing subgroups of participants who differed significantly in terms of their SF-12 summary scores (PCS and MCS), we found that the PMSIS can discriminate between groups with differing HRQOL. This is a critical form of validation, as the intent was to develop an instrument that assesses the impact of premenstrual symptoms on HRQOL domains. Although the instrument is, by definition, not a screening tool for detecting PMDD or clinically significant PMS, by using the retrospective criteria of the DSM-IV-TR definition of PMDD (and combined criteria from the DSM-IV-TR and ACOG for defining clinically significant PMS), we found that the PMSIS was able to discriminate between those participants who were at risk for these conditions and those who were not. For instance, a cutoff score of 48 on the PMSIS yields a sensitivity of 0.84 and specificity of 0.87 in detecting participants at risk for PMDD. It is important to remember that these women did not receive a formal diagnosis of PMDD and that our study design only permitted gathering data that could be used to evaluate the retrospective component of the DSM-IV-TR criteria. Further, the DSM-IV-TR criteria require

PMDD symptoms to occur over the past 1 year, along with a prospective evaluation of symptoms during at least two consecutive symptomatic cycles.

A limitation of our study was that respondents were asked about their symptoms over the past 3 months. It is, therefore, important that our results should be confirmed in a sample where both retrospective and prospective criteria are considered using validated instruments, such as the DRSP that screens for PMDD symptoms and the daily symptom report that screens for PMS symptoms. Given the limitations of the study, it is interesting to note that our prevalence rate for those at risk for PMDD (6.0%) is consistent with epidemiological numbers reported in the literature (ranging from 4.6% to 8.1%) using both retrospective and prospective reporting.[1,3,4,6,7] The same is true of the observed 17.3% prevalence rate for those at risk for clinically significant PMS, where the literature ranges from reports of 12.6% to 31.0%.[1,3,4,6,7] In conducting this cross-sectional study, we administered the item bank questions over the Internet. Although data collection over the Internet can be subject to a volunteer effect type of selection bias, the generalizability of our results is not limited because our sample came from a nationally representative female population of web users. Moreover, our collection of data via the Internet is justified, as the PMSIS is intended to be a web-based educational tool.

The use of the PMSIS might serve a number of different stakeholder groups. Consumers may use the instrument to evaluate the impact of their premenstrual symptoms on daily functioning and quality of life and receive norm-based feedback that can then be shared with their medical provider. Public health researchers may find the instrument useful for understanding the degree to which premenstrual symptoms that are below standard diagnostic criteria create an HRQOL or economic burden to reproductive aged women. To our knowledge, this is the first assessment tool designed to measure the functional impact of premenstrual symptoms on quality of life that has been validated against both HRQOL and relevant clinical gold standards.

REFERENCES

1. Sternfield B, Swindle R, Chawla A, Long S. Kennedy S. Severity of premenstrual symptoms in a health maintenance organization. Obstet Gynecol 2002;99: 1014.
2. American Psychiatric Association. Diagnostic and statistical manual of mental disorders, 4th ed, text revision (DSM-IV-TR). Washington, DC: American Psychiatric Press, 2000:771.
3. Steiner M, Macdougall M, Brown E. The premenstrual screening tool (PSST) for clinicians. Arch Womens Ment Health 2003;6:203.
4. Gehlert S, Hartlage S. A design for studying the DSM-IV research criteria of premenstrual dysphoric disorder. J Psychosom Obstet Gynaecol 1997;18:36.
5. Hylan TR, Sundell K, Judge R. The impact of premenstrual symptomatology on functioning and treatment-seeking behavior: Experience from the United States, United Kingdom, and France. J Womens Health Gend based Med 1999;8:1043.
6. Angst J, Sellaro R, Merikangas KR, Endicott J. The epidemiology of perimenstrual psychological symptoms. Acta Psychiatr Scand 2001;104:110.
7. Wittchen HU, Becker E, Lieb R, Krause P. Prevalence, incidence, and stability of premenstrual dysphoric disorder in the community. Psychol Med 2002;32:119.
8. Halbriech U, Borenstein J, Pearlstein T, Kahn LS. The prevalence, impairment, impact, and burden of premenstrual dysphoric disorder. Psychoneuroendocrinology 2003;28:1.
9. Pearlstein TB, Halbreich U, Batzar ED, et al. Psychosocial functioning in women with premenstrual dysphoric disorder before and after treatment with sertraline or placebo. J Clin Psychiatry 2000;61:101.
10. Borenstein JE, Dean BB, Endicott J, et al. Health and economic impact of the premenstrual syndrome. J Reprod Med 2003;48:515.
11. Borenstein J, Chiou CF, Dean B, Wong J, Wade S. Estimating direct and indirect costs of premenstrual syndrome. J Occup Environ Med 2005;47:26.
12. Ware JW, Kosinski MA, Turner-Bowker DM, Gandek B. How to score version 2 of the SF-12 health survey. Lincoln, RI: QualityMetric Incorporated, 2004.
13. Endicott J, Nee J, Harrison W. The daily record of severity of problems: Reliability and validity. Arch Womens Ment Health 2006;9:41.
14. Freeman EW, DeRubeis RJ, Rickels K. Reliability and validity of a daily diary for premenstrual syndrome. Psychiatry Res 1996;65:97.
15. Moos RH. The development of a menstrual distress questionnaire. Psychosom Med 1968;30:853.
16. Cronbach LJ. Coefficient alpha and the internal structure of tests. Psychometrika 1951;16:297.
17. Hu L, Bentler PM. Cutoff criteria for fit indexes in covariance structure analysis: Conventional criteria versus new alternatives. Structural Equation Modeling 1999;6:1.
18. Kerlinger FN. Foundations of behavioral research. New York: Holt, Rinehart, & Winston, 1973.
19. American College of Obstetricians and Gynecologists (ACOG). Premenstrual Syndrome. Washington, DC: ACOG, 2000, vol. 15.
20. Endicott J, Halbreich U. Retrospective reports of premenstrual depressive changes: factors affecting con-

firmation by daily ratings. Psychopharmacol Bull 1982;18:109.
21. Haywood A, Slade P, King H. Assessing the assessment measures for menstrual cycle symptoms: A guide for researchers and clinicians. J Psychosom Res 2002;52:223.
22. Steiner M, Streiner DL, Steinberg S, et al. The measurement of premenstrual mood symptoms. J Affect Disord 1999;53:269.

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Respondent's Name/ID

APPENDIX: PREMENSTRUAL SYMPTOMS IMPACT SURVEY

This survey asks you questions about how your premenstrual symptoms impact things you do every day. Premenstrual symptoms refer to symptoms that occur 5–7 days before the onset of your menstrual period and go away when your menstrual period begins or shortly thereafter. Please indicate your experiences during your last premenstrual period.

You are the expert on how premenstrual symptoms affect what you are able to do and how you feel. Please select the answer that best describes the impact of your premenstrual symptoms on your daily activities. If you are not sure about a question, please give the best answer you can. Thank you for completing this survey!

For each of the following questions, please mark an ☒ in the one box that best describes your answer.

1. During your last premenstrual period, how much of the time did you feel frustrated because of your premenstrual symptoms?

None of the time	A little of the time	Some of the time	Most of the time	All of the time
▼	▼	▼	▼	▼
☐	☐	☐	☐	☐

2. During your last premenstrual period, how much of the time did you have mood swings (e.g., suddenly felt sad or angry) because of your premenstrual symptoms?

None of the time	A little of the time	Some of the time	Most of the time	All of the time
▼	▼	▼	▼	▼
☐	☐	☐	☐	☐

3. During your last premenstrual period, how much of the time did your premenstrual symptoms limit your ability to concentrate on work or daily activities?

None of the time	A little of the time	Some of the time	Most of the time	All of the time
▼	▼	▼	▼	▼
☐	☐	☐	☐	☐

4. During your last premenstrual period, how often did you get tense (e.g., anxiety, muscular tightness) because of your premenstrual symptoms?

Never	Rarely	Sometimes	Often	Very Often
▼	▼	▼	▼	▼
☐	☐	☐	☐	☐

5. During your last premenstrual period, how much of the time did your premenstrual symptoms leave you too tired to do work or daily activities?

None of the time	A little of the time	Some of the time	Most of the time	All of the time
▼	▼	▼	▼	▼
☐	☐	☐	☐	☐

6. During your last premenstrual period, how often did your premenstrual symptoms keep you from socializing?

Never	Rarely	Sometimes	Often	Very Often
▼	▼	▼	▼	▼
☐	☐	☐	☐	☐