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<u>gearnette Sprithfaul 10/26/95</u> PT - Signature Date

FINAL REPORT

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(5) INTRODUCTION:

a. Nature of the problem.

Surveys of symptoms in the general population demonstrate a 30-87% prevalence of some premenstrual symptoms (1,2,3), whereas severe manifestations are reported in only 2-8% of women (1,2,4). The full-blown premenstrual syndrome (PMS) incorporates a constellation of behavioral, physical and psychological symptoms, including irritability, breast tenderness, sensation of bloating and/or nausea, decreased energy, and difficulty concentrating.

With 1) the current drawdown of the armed forces, 2) the percentage of women on active duty in the armed forces increasing, and 3) the scope of their duties recently expanded to include many combat-related military occupational specialties, it is crucial to determine whether simple lifestyle changes could impact a known gynecologic condition with adverse physical and psychological implications for combat readiness. Any syndrome that may worsen with added stressors, and which can affect job performance would have a profound impact on unit function. This project was designed to gather information to use in developing recommendations for treatment and symptom reduction (for example, nutrition or activity counseling).

b. Background of previous work.

Nutrition

Alterations in appetite and taste preferences for specific foods across the menstrual cycle are common manifestations of PMS and suggest the potential impact of nutritional factors on this syndrome (5 - 9). Symptoms increase in proportion to ingestion of tea, coffee, and alcohol (10,11). The effect of carbohydrate intake on mood in PMS has also been explored (7,9,12,13). Consumption of a carbohydrate-rich, protein-poor evening test meal during the late luteal phase of the menstrual cycle improved depression, tension, anger, confusion, sadness, alertness and calmness scores; providing a possible explanation for the carbohydrate craving experienced by some women.

Exercise

Studies have evaluated the effects of exercise on hormonal levels in women. Schwartz et al reported that the most common hormonally related change noted by women runners was a decrease in premenstrual symptoms (14). College students who underwent aerobic training manifested significantly reduced menstrual cycle symptoms and lower scores on the Moos Menstrual Distress Questionnaire following aerobic training than their sedentary counterparts (15). Postulated reasons for the decrease in symptoms are less pelvic congestion due to the shunting of blood flow away from the viscera to the working muscles and/or the analgesic effect of exercise-induced beta endorphin levels (16).

Some studies have suggested that exercise may relieve or reduce premenstrual symptoms (14,15,17). The exercise parameter that correlated most frequently with perimenstrual symptoms was duration or the number of months one had been exercising at the current level. More recently, a small, prospective, controlled, three-month trial of eight women doing conditioning exercises showed a significant decrease in overall molimina (particularly breast tenderness and symptoms of water retention) with moderate exercise training (approx. 50 km/cycle running) without concomitant weight loss or menstrual cycle alteration (17). <u>Stress</u>

Several studies have yielded a positive correlation between perimenstrual symptoms and chronic stress (18,19,20). Stress correlated significantly with most measures of perimenstrual symptoms, but the correlations were small and accounted for only 3% to 15% of the variance. General physical symptoms correlated more closely with the stress of daily hassles than with the stress of major life events.

c. Purpose of present work.

This study was designed to determine (1) whether there is an association between physical activity and the prevalence of premenstrual symptoms in a diverse uniformed and civilian population; (2) whether stress affects the incidence of premenstrual symptoms; and (3) whether nutrition positively or negatively affects symptoms.

d. Methods.

Computer assisted telephone interviewing (CATI) was used to obtain information on premenstrual symptoms, physical activity, stress, and dietary intake. The Cohen Perceived Stress Scale and the Shortened Premenstrual Assessment Form (PAFS) were incorporated into the interview (21,22). Because insufficient numbers of subjects were obtained by advertising in the metropolitan Washington, DC area, interviewing was subcontracted to the Survey Research Laboratory (SRL) at Virginia Commonwealth University (VCU) in Richmond, Virginia - the parent institution of one of the principal investigators (TA). The interviewing was conducted between 4 August and 10 September 1995.

Information on presence and severity of PMS was obtained by using the Shortened Premenstrual Assessment Form (PAFS) - a 10-item scale adapted and validated from a 95-item questionnaire originally developed by Halbreich in 1982 (23,22). The severity of PMS during the week before menses was rated by each respondent as "1=not present at all," "2=mild," "3=moderate," or "4=severe." For each respondent the sum of these scores constituted the PAFS score.

Activity questions focused on specific activities during the week and on weekends. Subjects were asked to note specific distances or duration of recreational and occupational activities. Physical activity was assessed on a six-point scale ranging from "very low" to "very high" activity levels.

Factors considered as covariates of PMS were dietary intake, stress, and socio-demographic factors. The role of diet in the etiology of PMS was assessed by utilizing a food frequency survey. Questions on carbohydrate and caloric intake, foods and beverages that are high in sugar and caffeine were included.

The Perceived Stress Scale was developed as a 14-item measure of the degree to which situations in one's life are appraised as stressful (21). This scale was designed to tap the degree to which respondents find their lives unpredictable, uncontrollable, and overloading. These three issues have been consistently found to be central components of the experience of stress.

(6) **BODY**:

a. Study population and data collection

A five-part questionnaire was administered to women volunteers aged 18 - 44 residing in the state of Virginia to test the hypothesis that there is no association between physical activity and premenstrual symptoms.

The sampling frame consisted of 7900 RDD telephone numbers for the state of Virginia. The sample was prepared by GENESYS Sampling Systems in Fort Washington, PA and was designed so that all telephones, including new

and unlisted numbers, had an equal and known probability of inclusion in the sample frame. GENESYS assigns to each and every possible area code, exchange, and four digit suffix of the sampling frame a known and equal probability of selection. Once the sample was pulled from the sampling frame, all exchanges that would be nonproductive were selected out (e.g. by purging all non-residential yellow page businesses.

Of the 7900 numbers in the sampling frame, 1700 households with eligible respondents were reached. Seventy-six of the households contacted had language difficulties which made completion of the survey impossible, 23 were too ill to complete the survey, 422 refused to complete the survey, 263 were scheduled to be called back after the study was completed and were therefore never recontacted, and 42 respondents were gone for the duration of the study. Interviews were obtained with 51.4% of the women between 18 and 44 years of age contacted, resulting in a total of 874 respondents.

Based on information from the U.S. Census Bureau's 1990 census, it was estimated that approximately 15 percent of the households in the sample would have incomes below \$15,000. After 700 survey completions, only 11% of the sample were in the low income category. Therefore, it was decided that households would be screened for eligible women with household incomes below \$15,000. This was done until a minimum of 100 households in this income category were completed.

The final data were then weighted based on the 1990 Public Use Microdata Sample (PUMS) - 5% file of the U.S. Census Bureau. Weighting was based on respondents' age, race, and household income. By weighting the data, the age distribution of respondents, race distribution and household income distribution would more accurately represent what would be expected in a true random sample of the population of wommen in Virginia between the ages of 18 and 44.

Questions answered by the entire sample of 874 subjects are subject to a sampling error of plus or minus approximately 4 percentage points at the 95 percent level of confidence. This means that in 95 out of 100 samples like the one used here, the results obtained should be no more than 4 percentage points above or below the figure that would be obtained by interviewing all women in the target age group in Virginia. Where the answers to subgroups are reported, the sampling error is higher.

Due to non-response, such as through an eligible respondent's refusal to participate, standard calculations of sampling error may understate the actual extent to which survey results are at variance with true population values. Surveys are also subject to errors from sources other than sampling (e.g. response bias, respondent's misinterpretation of the question, etc.). While every effort is made to identify such errors, they are often difficult or impossible to measure.

b Statistical Analysis

Several statistical methods were used for data summarization and hypothesis testing. When both physical activity levels and severity of PMS were represented on ordinal scales, log-linear models were used (50). These models are useful in uncovering the potentially complex relationships among the variables in a multi-way cross-tabulation. In general, the model for the observed frequency in the ith row and the jth column is given by:

Ln $F_{ij}=\mu + |Hi + |Sj + |HSj|$

where F_{ij} is the observed frequency in the cell, IHi is the effect of the ith row category, ISj is the effect of the jth column category, and IHSj is the interaction effect for the ith value of the row category, and the jth value of the column category.

If PMS is measured on an ordinal scale (e.g. "not present at all" to "severe symptoms") and physical activity is expressed as a dichotomous variable (e.g. high vs. low activity levels) the Mann-Whitney U statistic was bused (51). It provides a direct estimate of the probability that a woman will have low PMS symptoms if she has 'high' physical activity level. Alternatively, a two sample t-test can be used as an approximation of the Mann-Whitney U test to compare the two groups if ordered numerical values (i.e. PAFS scores) are assigned to the two groups.

When PMS was expressed as a dichotomous variable, and physical activity as ordinal variable, the prevalence odds ratio was used as the measure of association between physical activity and PMS. It is defined as the ratio of the odds of a higher level physical activity to that of a lower level. Unconditional logistic regression modeling were used to control for confounding and 95% confidence intervals will be computed to reflect the statistical precision of the prevalence odds ratio estimates (52).

c. Sample Size

Sample size for this study was calculated under the assumption that: (a) the prevalence of PMS is 5% in women with low physical activity scores; (b) the closest value that we will be able to distinguish in women with low physical activity scores is 1.0%, i.e. any value of 1.0% or lower would give a pvalue of .05 or less. This corresponds to an odds ratio of 0.2. Under these assumptions, the estimated sample size will be 664. If we, further, assume a participation rate of 80%, the final sample size needed will be 664 x 100/80 =830 women.

d. Results

In preliminary analysis, activity did not seem to be as significant a factor on PMS as thought. The data available at this point show crude estimates since we have not yet controlled for confounding variables.

To determine the overall prevalence of premenstrual syndrome in the total population, women responding to the Shortened Premenstrual Assessment Form (PAFS) as experiencing extremely severe or severe (scores of 5 or 6) symptoms were compared to those recording all other categories (1, 2, 3, or 4). The overall prevalence of PMS is 10.4%. Eleven (11.9%) of white subjects and 5.3% of African American subjects are in this category. The prevalence ratio of whites to African Americans is 2.2.

The remaining data were analyzed by comparing subjects with extremely severe or severe symptoms to subjects with no or minimal symptoms (Table 1). No significant differences relative to educational attainment were evident. Subjects noting church attendance at least twice monthly were 2.5 times less likely to manifest PMS. For divorced or separated women, the rate of PMS is substantially higher than either married or single women.

Smokers are 3.3 times more likely to report severe premenstrual symptoms than nonsmokers. Those taking vitamins regularly are 2.1 times less likely to complain of PMS than those who do not, but the numbers responding were small. Coffee consumers are 1.7% more likely to report PMS than non-coffee drinkers. Beer, wine, and liquor consumers similarly have a

1.7 prevalence ratio of PMS compared to those who do not drink. No significant relationships between ingestion of tea, sugar and carbohydrates, and fat and PMS are seen.

(7) CONCLUSIONS:

This pilot project can be used as baseline information for comparison in determining whether women on active duty are at increased risk for premenstrual symptoms (since no such study has been done before). Variables which seem to be the most significant will be examined using multivariate analysis to control for age and other confounding variables. When controlling for age or other variables, these changes may disappear or appear greater.

The prevalence of extremely severe or severe premenstrual symptoms (arbitrarily defined as PMS) found in this study are consistent with that reported in the literature (i.e. 2 - 10% of the population) (12). If only subjects experiencing extremely severe premenstrual symptoms were defined as having the syndrome, the prevalence would be 1.8% (scores of 6 only on PAFS). If those reporting extremely severe or severe symptoms constituted those with the syndrome, the prevalence would be 10.4% as noted above (scores of 5,6). The prevalence of those reporting moderate symptoms or above (scores of 4,5,6) is 65.7\% of the population.

Further analysis on the activity data is needed to determine whether age, ethnicity or other factors together with activity impact on the manifestation of premenstrual symptoms. Previous studies of the impact of exercise on premenstrual symptoms have involved small numbers of subjects and should be repeated (16,17,23,24).

Nevertheless, preliminary data suggest that certain behaviors are associated with substantial additional risk of premenstrual symptoms and/or the syndrome. Modification of use of tobacco, diet, and alcohol may be beneficial to those women with significant symptoms each month.

Because the majority of subjects were civilians, a follow-up project is planned to survey uniformed women regarding prevalence and management of premenstrual symptoms.

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Syndrome			
Characteristics	Total (%)	Prevalence of PMS % (5,6/1,2)	Prevalence Ratio
Race White Black Other	210 (70.2) 70 (23.2) 19 (6.6)	7.8 1.4 5.3	5.6 1.0 3.8
Education LT High school High school diploma Some college College grad Graduate or prof	22 (7.3) 80 (26.8) 74 (24.8) 99 (33.2) 23 (7.8)	6.3 7.3 4.7 5.8 8.3	1.0 1.2 0.7 0.9 1.3
Church attendance Yes No	169 (56.1) 132 (43.9)	3.7 9.2	1.0 2.5
Marital status Manied Single Divorced/Separated	186 (61.9) 84 (28.1) 30 (10.0)	6.0 3.5 12.9	1.7 1.0 3.7
Family Income Under \$15,000 \$15,000-\$19,999 \$,20,000-\$34,999 \$35,000-\$49,999 \$50,000 and above	42 (15.5) 19 (7.0) 61 (22.3) 51 (18.6) 100 (36.7)	7.4 19.6 6.5 2.0 6.7	1.0 2.6 0.8 0.3 0.9

Table 1. Socio-demographic Factors and Premenstrual

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Occupation			
Employed for wage	195 (65.2)	6.4	1.0
Self-employed	11 (3.7)	8.8	1.4
Out of work	17 (5.7)	11.8	1.8
Homemaker	59 (19.8)	2.4	0.4
Student	14 (4.8)	7.9	1.2
Unable to work	2 (0.8)	0.0	

Table 1 C ais Jamassankia Fastars and Promonstrual

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Characteristics	Total (%)	Prevalence of PMS	Prevalence Ratio
Smoke ciagrettes			
Yes	150 (41.0)	11.5	3.3
No	230 (60.4)	3.5	1.0
Vitamîn use			
Yes	75 (60.7)	5.6	1.0
No	49 (39.3)	11.8	2.1
Activity weekend			
LT 2 hrs	55 (18.5)	11.2	0.5
2-3 hrs	87 (29.6)	5.7	1.0
GE 4 hrs	153 (51.9)	5.2	0.9
Activity			
Sedentary	71 (23.7)	2.7	1.0
Irregular	78 (26.2)	8.1	3.0
Kegular	150 (50.2)	б.8	2.5
Felt stressed			
Never/almost never	83 (27.7)	1.2	1.0
Sometimes	114 (38.2)	2.3	1.9
Fairly often	46 (15.2)	5.5	4.6
Very often	57 (18.9)	21.7	18.1

Table 2. Lifestyle, Physical Activity, Dietary Factors and PremenstrualSyndrome

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