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Association of Fatigue and Preterm Birth in Active Duty Military Women

by

Janice Chiyomi Stinson

DISSERTATION

Submitted in partial satisfaction of the requirements for the degree of

DOCTOR OF PHILOSOPHY

in

Nursing

in the

GRADUATE DIVISION

of the

UNIVERSITY OF CALIFORNIA

San Francisco



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by

Janice Chiyomi Stinson

Dedication

This work is dedicated to my dear husband, Lieutenant Commander Ralf Hale Stinson, II, United States Navy, Retired, who offered tremendous support and patience with my academic tasks over the last five years, to my parents, Noboru and Elaine Kawamoto whose guidance in discipline and the value of education helped me persevere through all the challenges of doctoral study and to my mother-in-law, Harriett Stinson, whose caring and generosity helped me focus on key issues and the completion of the dissertation.

Acknowledgments

I would like to acknowledge the people without whose assistance this work, the culmination of my four and a half years of doctoral studies at the University of California, San Francisco, would not have been possible.

First, I would to thank Dr. Kathryn Lee for her superb mentorship. She provided a model of scholarliness as dissertation committee chair and advisor and numerous opportunities to hone my skills as a novice researcher.

Second, I would my deep appreciation to members of the dissertation committee, Drs. Jeanne DeJoseph and Nanny Murrell. Their critiques provided valuable perspectives to this research, providing a very rich, productive dissertation experience. Drs. Steven Paul and Peter Bacchetti were also extremely helpful in providing statistical advice.

Third, I would like to thank the various local principal investigators for assistance in helping me through the institutional review process and data collection: Captain Peggy McNulty, Naval Medical Center, San Diego; Commander Bennett Leshnover, Naval Medical Center Portsmouth; Major Nanette Liberatore, Tripler Army Medical Center; and Major Lynn Bricca and Major Sherie Rawls-Bryce of David Grant Medical Center, Travis Air Force Base. I would also like to recognize the project directors at each site: Patrick McNulty, San Diego; Lieutenant Commander Christine Lenoir, Portsmouth; and Susan Dizon, Tripler. Research assistants who did provided me with valuable data included: Lieutenant Terry Zawacki, Lieutenant Susan Parker, Lieutenant Laura Padilla, Twila Nelson and Brenda Kittrell at Portsmouth, Judy Carol at San Diego and Lee Deir, Nelofar Zandani and Charlotte Hammock at Tripler. I appreciate the additional research assistants for the chart review portion of the study including Mary Ann Paul, San Diego;

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Captain Lori Trego, Tripler and Second Lieutenant Deborah Ford of David Grant and Aeron Cho and Marge McCandless who assisted with data entry.

Many thanks are extended to fellow doctoral students Hee Jeong Kim, Jeanne Kemppainen, Lieutenant Colonel Stacey Young-McCaughan, Major Darlene Gilchreast and Major Kathryn Dolter who took special interest in this research and whose support provided me with the sustained energy to complete the project.

I appreciate my daughters, Sara Akiko Stinson and Erika Emiko Stinson, cheering me on with smiles and e-mail during periods of joy and frustration.

And finally, I want to thank the military women who volunteered to be a part of this research. Their enthusiasm and interest in the protocol, including the filling out of diaries and keeping in touch through the last months of their pregnancies was admirable and contributed valuable information for all working pregnant women.

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Janice Chiyomi Stinson

Captain, Nurse Corps, United States Navy Reserve 29 May 1997

ASSOCIATION OF FATIGUE AND PRETERM BIRTH IN ACTIVE DUTY MILITARY WOMEN

Janice Chiyomi Stinson

University of California, San Francisco, 1997

The purposes of this study were to: 1) describe the internal and external environmental demands of fatigue correlates in pregnant military women, and 2) determine the relationship between fatigue at 22-26 weeks gestation and the incidence of preterm labor and birth in military women. Inclusion criteria included those designed to minimize confounders for preterm labor and delivery such as no history of preterm delivery. Data were collected prospectively at 22-26 weeks gestation by questionnaires including the Profile of Moods States, Visual Analog Scale-Fatigue, Sleep Disturbance Scale, Life Events Questionnaire, Support Behavior Index, and Occupational Fatigue Index (OFI). A fatigue diary was completed over 2 consecutive work days and mailed back to the Principal Investigator. Telephone follow up of hours worked per week was conducted until the participants delivered. Postpartum charts were reviewed for pregnancy outcomes. The sample consisted of 359 women, predominantly White (62%), enlisted (91%), Navy (72%) with a mean age of 23.9 years.

Hierarchical linear regression models with 11 variables explained 36% of the variance in fatigue while 14 variables explained 30% of the variance in energy. Independent variables making unique contributions to fatigue severity perception were sleep disturbance, negative life events and role demands. Hierarchical logistic regression models revealed no significant relationship between preterm birth (9.5%) and fatigue

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severity or occupational fatigue but a trend toward lower fatigue severity ($\chi^2 = 3.78$, p=.0552) and posture subscale of the OFI (χ^2 =2.39, p=.12) with preterm labor (13.6%). When placed in multivariate models, neither fatigue or occupational fatigue were related to preterm labor and birth. However, officer rank was associated with both preterm labor (OR=2.75, 95% CI=1.08, 6.98) and preterm birth (OR=4.14, 95% CI=1.54, 11.08). Low sleep disturbance (OR=2.36, 95% CI=1.09, 5.07) and negative life events (OR=1.05, 95% CI=1.01, 1.08) were also related to preterm labor.

These findings suggest that the military woman who is at risk for preterm labor is a high energy officer experiencing stress and that fatigue is protective against premature birth. The results support investigation of interventions which examine the pregnant officer and activities in a high energy group which may lead to preterm labor.

Candidate

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CHAPTER 1

THE STUDY PROBLEM

Introduction

Preterm birth, defined as the birth of a fetus before 37 weeks gestation, occurs in about 9% of single live births in the United States but accounts for between 50 and 70% of total perinatal mortality and morbidity (De Haas et al., 1991; Hoffman & Bakketeig, 1984). Despite major advances in obstetric care, the incidence of preterm delivery has remained constant over the last three decades (Heffner et al., 1993) due to the lack of physiological knowledge concerning the mechanism of labor and ineffective therapies for premature labor (Simpson, 1993). Without this knowledge of the underlying causes of the initiation of parturition, medical providers have turned to approaches used to identify women at risk for delivering early. These approaches have included investigation of obstetric history, demographic characteristics, daily habits and clinical findings during the current pregnancy (Creasy et al., 1980).

Prior preterm labor and delivery and spontaneous abortion (Kramer, 1991), prior chronic illnesses, multiple gestation (Main, 1988), vaginal colonization with bacterial vaginosis or Chlamydia trachomatis and urinary tract infections (Arias, 1993) are all factors implicated in preterm labor and birth. These factors, however, are difficult to modify. African American ethnicity, single marital status and poverty (Kleinman & Kessel, 1987) are also factors associated with shortened duration of pregnancy. But, as demographic variables, interventions to alter these variables' effects have had limited success (Creasy, 1991). An approach which identifies modifiable factors during pregnancy may lead to more effective nursing interventions to minimize the risk of preterm birth.

Main and Gabbe (1987) have identified five lifestyle risk factors associated with preterm birth that can be modified: substance use (smoking, alcohol, illegal drug intake), poor weight gain, absent or inadequate prenatal care, heavy physical labor and psychological stress. A sample of active duty military women restricts the study to a relatively homogeneous population based on these five risk factors since enlistment standards result in a moderately educated, physically fit and essentially disease-free sample (Irwin et al., 1994; Institute of Medicine, 1995). This population also has optimal access to prenatal care (Kugler et al., 1993) and minimal illegal drug use (Brunader et al., 1991; Polzin, Kopelman , Brady, & Read, 1991)). However, the active duty female, with few exceptions, is expected to perform all duties not detrimental to her pregnancy until the onset of labor (Magann & Nolan, 1991). Therefore, this enables one to focus on the fatigue of physical work and psychological stressors as biologically plausible factors (Lockwood, 1994; Luke et al. 1995) that could be associated with preterm labor and birth.

Statement of the Problem

The exact nature of fatigue's relationship to adverse pregnancy outcomes such as preterm labor or birth is unclear. Numerous studies of employment and psychological stressors as proxies for fatigue have shown conflicting results. Some studies have shown that work outside the home results in shortened gestation (Alegre et al. 1984; Mamelle et al., 1984; Teitelman et al., 1991). Other studies have shown no connection between maternal work and birth outcome (Berkowitz et al., 1983; Klebanoff, Shiono, & Carey, 1990). The presence of unidentified socio-economic differences leading to varying access to prenatal care (Fiscella, 1995), misclassification of job titles (Henriksen, Hedegaard, & Secher, 1994), biased recall (Berkowitz & Papiernik, 1993), lack of consideration of significant factors such as family function (Kugler, et al., 1993) and insufficient power for detecting an effect in some studies (Magann et al, 1995a) are possible explanations for the inconsistent findings.

More recently, however, there has been one study comparing 80 high risk and low risk mothers in a university clinic population (Pitzer, 1994) showing a significant relationship between fatigue and preterm birth in the high risk group of 40 women. This study needs prospective replication in populations of women such as those in the military who experience considerable amounts of physical and mental exertion while controlling for potential confounders such as prenatal care access, maternal health and history of preterm birth and illicit drug use. Research on military women and adverse pregnancy outcomes have focused on the number of hours worked per week and duration of work during pregnancy (Messersmith-Heroman et al, 1994) or job categories (Ramirez et al., 1991; Adams et al., 1993; Magann et al., 1995a). No studies have been done on military active duty women, their perception of fatigue, their level of occupational fatigue and the incidence of preterm labor or birth.

Purpose of the Study

The purpose of this research was to: 1) describe the external environmental demands (marital status, social support, housing, occupation, rank, life events, race) and internal environmental demands (age, nutritional status, weight gain, smoking, alcohol, sleep disturbance, depression, anxiety) as correlates of fatigue in pregnant active duty women; 2) determine the relationship between perception of fatigue severity at 22-26

weeks gestations gestation and the incidence of preterm labor and birth in active duty women; and 3) determine the relationship between the level of self reported occupational fatigue at 22-26 weeks gestation in active duty women and the incidence of preterm labor and birth.

Significance of the Problem

Recent studies of military pregnancies in the United States (U.S.) have documented the preterm delivery rate for Army enlisted women (Adams et al. 1993) and Navy enlisted women stationed aboard combat ships (Spandorfer et al., 1996) at 12% while Air Force active duty women showed a 17% preterm birth rate at 3 major medical centers (Retrospective Case Mix Analysis System data base, 1995) which is much higher than the national average of 9%. Moreover, a recent study (Spandorfer et al., 1995) showed a 16% rate of active duty pregnancies which resulted in the admission of neonates to the Neonatal Intensive Care Unit (NICU). Neonatal intensive care is clearly the most expensive health care service in our present health care system (Morrison, 1990). Five million hospital days per year are needed in the care of preterm offspring with yearly NICU costs exceeding \$5 billion. The proportionate costs of cancer, myocardial infarction or renal transplants have not risen as dramatically as the cost of neonatal intensive care. Besides the cost of NICU care, there is also a high price paid for lost hours and productivity of active duty women who need to be placed on bedrest once diagnosed with preterm labor and additional time spent postpartum for infants who require care and attention.

Despite the significance of this problem, the cause of preterm labor and delivery is not known in up to 65% of cases (Colie, 1993). The lack of knowledge concerning the physiological mechanism of premature labor limits our effectiveness in recognizing and treating early labor and subsequent delivery. The investigation of every available intervention that could reduce preterm birth is crucial given the medical, social and economic costs in identified "at risk" populations (Creasy, 1991).

With nearly 200,00 female members on active duty in the U.S. military services (Institute of Medicine, 1995) and the physical and psychological demands imposed by military service (King et al., 1993), the active duty female is at risk for adverse pregnancy outcomes (Fox et al., 1977; Magann & Nolan, 1991). This study will contribute significantly to nursing science by focusing on this physically active homogeneous population with similar socio-demographic and working characteristics, thereby identifying dimensions and correlates of fatigue with a possible linkage to preterm labor or birth. Study results will provide data to begin developing a theoretical framework for military women at risk for shortened gestation. Furthermore, the data empirically support recommendations for care of all working women who plan pregnancies for the critically important need to prevent preterm labor and birth. The dramatic increase of women's presence in the workforce from less than 30% in the 1950's (Chamberlain, 1993) to over 70% working outside the home in the 1995 (Luke et al., 1995) together with the Healthy People 2000 priority of reduction in preterm births (U.S. Department of Health and Human Services, 1990) increases the importance of investigating the potential adverse effect of occupational factors on reproductive outcomes.

CHAPTER TWO

LITERATURE REVIEW

Introduction

Despite the importance of the possible link between fatigue and preterm delivery, it is still considered a subtle relationship (Pitzer, 1991) because of the lack of understanding of its physiological and epidemiological complexity. The purpose of this chapter is to: 1) define fatigue for the purpose of this study, 2) describe the plausible physiological mechanisms of fatigue and preterm labor and delivery, 3) critically evaluate the Environmental Demands Fatigue Model which contains relevant epidemiological factors associated with fatigue and preterm labor and birth and 4) examine pertinent literature relevant to the model's variables and links.

Definition of Fatigue

There have been a number of attempts to define fatigue. Fatigue has been described historically as a multi-dimensional, complex phenomenon with various physiological and psychological components (Piper et al., 1987). It has been defined by Hart and Freel (1982) as a state of increased discomfort and decreased efficiency due to expenditure of energy reserve. It has been depicted as a biological reaction with decreased neurotransmitters resulting in an inability of muscle cells to contract (Tsaneva & Markov, 1971), a generalized response to stress extending over a period of time (Cameron, 1973; Fagley et al., 1982) or the non-specific state indicative of decreased vitality (Grandjean, 1970). From a psychological prospective, fatigue has been described as a subjective symptom of lack of energy related to decreased motivation, depression, anxiety, prolonged mental activity and boredom (Lee et al, 1994; Pugh & Milligan, 1993). Fatigue, furthermore, appears in both the ill and healthy (Potempa, 1993), can be acute or chronic (Kellum, 1986), can be generalized or muscle fiber specific (Piper, 1986) or can be viewed on a continuum from vitality to exhaustion (Grandjean, 1970; Lee et al., 1994).

For this study on pregnant active duty women, fatigue severity is defined as a generalized, subjective perception of lack of energy. It can further be conceptualized as perceived on a continuum of various levels of tiredness which may change at different times of the day in response to the stressors of pregnancy (Lee et al., 1994). It is "generalized" as it encompasses the whole person. It is "subjective" as fatigue is not based on neurotransmitter measures but, instead, on self-report of the individual. Fatigue is viewed on a "continuum and as a response to stressors" as tiredness does change through the day and through pregnancy depending on events that occur each day and in each trimester. Lee and associates (1991) showed that fatigue is significantly lower in the morning than in the evening (t=3.6, p<.001). Subjective perception of fatigue is especially high in the first trimester and often continues to be a complaint into the fourth month gestation (Fawcett & York, 1986; Van Lier et al., 1993) due to the progesterone levels which contribute a sedative effect. Fatigue levels decrease during the second trimester. Then, in the third trimester, fatigue levels increase due to physiologic demands of more body weight (Reeves et al, 1991; Lee & DeJoseph, 1992; Cherry, 1987). Two recent longitudinal studies have contradicted these traditional observations of second trimester energy increase. Pugh and Milligan (1995) in a study of 11 predominantly white, single, low income women and Lee and associates (1994) in the preliminary results of 18 mostly white, middle class, married women who had planned their

pregnancies found that their study participants experienced high levels of fatigue throughout their pregnancies. Though the sample sizes were small, these observations need to be further investigated.

What is unique about fatigue in pregnancy is its occurrence in what is basically a temporary disturbance in an acute, wellness condition. This implies that pregnancy fatigue is considered protective and normal in many cases, is expected with activities and is dispelled after restorative sleep (Fawcett & York, 1986). However, certain factors such as overwhelming physiological and psychological stressors without adequate resources to cope, may predispose the pregnant woman to a type of fatigue which may take on chronic or sustaining characteristics. Fatigue of this nature may no longer be protective, may interfere with the woman's self care activities, especially nourishment and hygiene, may persist over the entire course of the pregnancy and may not be relieved by sleep. It is this fatigue, though still poorly understood, that may predispose employed women to decreased performance in their multiple roles in their workplace as well as at home (DeJoseph, 1993) and, more seriously, to an inability to carry a pregnancy to term (Joffe, 1986).

The definition of fatigue severity also needs to be distinguished from occupational fatigue. Occupational fatigue refers to energy expenditure from physical activity (posture –standing, sitting, walking and physical exertion – lifting, reaching, bending), mental activity (concentration or lack of concentration required), and the work environment (work on industrial machines, humidity, cold, heat, chemical exposures). Other related variables which may contribute to occupational fatigue include transportation to and from work, number of hours per work day, working during hours before 0800 or after 1800,

number of days per week and consecutive days off between work days and speed of work (Florack et al., 1995). Occupational fatigue does not include energy demands originating from off the job, including the role demands of housework, volunteer work, recreation, child care and maintenance of a close adult relationship. Key related variables are number of children below 5 years old, stair climbing and the type of housing environment (eg. barracks, apartment, single detached house). For this study, these variables will be grouped under the external environmental demand, housing situation.

Physiological Mechanisms of Labor Onset

Current knowledge about the physiological etiology of labor (uterine muscle contractions resulting from hormonal stimuli stimulating calcium movement at the cell membrane leading to cervical change) consists of a number of theories. The first theory has to do with an increase in plasma oxytocin before or during early labor based on clinically successful uses of oxytocin to induce labor in near term pregnant women. However, it has been shown that plasma levels of oxytocin do not actually increase until the second stage of labor (Valenzuela et al. 1993) and prostaglandin levels (essential in the calcium movement noted above) do not increase during oxytocin induced labor (Padayachi et al. 1986). A second theory is that the fetus hypothalamus and adrenals actually signal the processes whereby prostaglandin agents increase in the amniotic fluid to stimulate labor. However, human anacephalic infants as well as those with congenital adrenal hypoplasia deliver at gestational ages not different from controls (Falcone & Little, 1994), diminishing the importance of the fetus as the originator of labor. A more popular theory considers local alterations in steroids that may trigger parturition. With an increase in estrogen and a decrease in progesterone, there are changes in prostaglandin

levels which enhance a number of uterine smooth muscle stimulating mechanisms (Lockwood, 1994).

Mechanisms of Preterm Labor

What exactly triggers the early hormonal cascade [increase in estrogenprogesterone ratio] that sensitizes the uterine myometrium to oxytocin and prostaglandins with subsequent enzymatic phosphorylation and dephosphorylation of myosin is not known (Lockwood, 1994). Moreover, with preterm deliveries, processes involving activation of cells in the cervix, decidua and fetal membranes appear to be similar to term deliveries—only the timing of the onset of each is different. However, three tentative initiating sources which lead to abnormal timing of labor have been identified: 1) decidual hemorrhage, 2) ascending genital tract infection and 3) maternalfetal stress.

Hemorrhage and Ischemia

Decidual hemorrhage results in preterm labor due to placental ischemia which either precedes or follows abruptio placenta. A tentative pathogenic explanation is that placental ischemia may enhance fetal corticotropin releasing hormone (CRH) to start the hormonal cascade leading to an increase in fetal adrenocorticotropic hormone (ACTH) and an increase in the estrogen-progesterone ratio. An increase in estrogen relative to progesterone leads to prostaglandin biosynthesis from esterified arachidonic acid stored in the trophoblastic membranes. The increased estrogen ration to progesterone enhances uterine activity in several ways: 1) PGE2 and PGF2 alpha activate increased uterine contractions by increasing calcium levels in the cytoplasm of the myometrium smooth muscle cells, 2) cervical collagenase increases which ripens the cervix, 3) oxytocin sensitivity increases via increase concentration of receptors which lower the threshhold for initiation of action potentials in muscle contractility and 4) gap junctions increase in myometrial tissue which enhances the transport of ions, metabolites and second messengers during a contraction (Garfield & Hayashi, 1981). Ischemia may also result from decreased uterine blood flow occurring with maternal hypertension and dehydration, and the vasoconstriction of placental blood vessels that occurs with substance abuse, in particular cocaine (Creasy, 1991).

Another explanation for decidual hemorrhage could be endocrine or paracrine factors which lead to reduced decidual hemostatic potential. Lockwood and associates (1993) have noted reductions in tissue factor (initiator of hemostasis) and mRNA expression responding to progesterone withdrawal. Progesterone withdrawal reduction of type-1 plasminogen activator will reduce decidual hemostatic potential while increasing its proteolytic activity to promote vascular instability and membrane rupture. It is not clear what endocrine or paracrine factor (including the role of fatigue) precedes the progesterone withdrawal leading to hemorrhage, triggering preterm labor.

Infection

A second major source of cervical-decidual-fetal membrane activation, not necessarily related to fatigue, is infection. Activation involves the production of cytokines in response to intrauterine macrophages (such as interleukin-1[IL-1] or tumor necrosing factor [TNF]). Cytokines are known to stimulating arachidonic acid metabolites (Myers & Nathanielsz. 1993). Cytokines also directly affect cervical ripening by enhancing cervical extracellular matrix (ECM) proteins protease activity. IL1-, itself, can stimulate placental CRH, suggesting an alternate paracrine route to activate preterm delivery (Lockwood, 1994). Hence, vaginal infection, by virtue of various pathways of stimulating prostaglandins and cervical change, is a major cause of preterm delivery but accounts for a relatively small percentage of preterm labor (Valenzuela et al., 1993).

<u>Stress</u>

A third biological explanation, most often quoted as a plausible connection between fatigue associated factors and preterm delivery, is the role of maternal-fetal stress in the release of various hypothalamic and adrenal stress hormones(Launer et al., 1990; Omer & Everly, 1988; Simpson, 1993; Stein et al., 1986; Naeye & Tafari, 1983; Ahlborg, 1995; Berkowitz & Papiernik, 1993; Bragonier et al., 1984; Teitelman et al., 1990; Berkowitz & Kasl, 1983; Katz et al., 1991). A variety of factors, including heavy physical work and fatigue, can cause stress and lead to increased CRH secretion. CRH augments prostaglandins produced by amnion, chorion and decidual cells and increases myometrial sensitivity to oxytocin (Quartero, 1989). Stress also results in the release of catecholamines which increase blood pressure and uterine irritability secondary to alpha adrenergic receptor stimulation (Main, 1988). There is also decreased placental function due to blood being shunted from uterine smooth muscle to striated muscles (Bragonier et al., 1984) resulting in the ischemic process described above.

Further support for this theory has been derived from other studies where standing posture under experimental conditions (not actually done in the work place) has been associated with increased uterine contractions due to obstruction of venous flow of pelvic vessels (Schneider et al., 1985), pressure on the cervix (Friedman & Sachtleben, 1977) and actual measurement of urinary free epinephrine and norepinephrine related to occupational stress (Timio, Gentili, & Pede, 1979; Katz et al, 1991).

Although the three possible sources of preterm labor have been described separately, they can all be thought of as interrelated. Severe fatigue due to physical exertion could lead to redistribution of blood flow and placental infarcts (Naeye & Peters, 1982) with resulting inadequate uteroplacental blood flow and ischemia. Fatigue may also alter the immunologic status of the pregnant woman. Fatigue sets off the alarm stage of the "General Adaptation Syndrome" (GAS), as originally described by Selye (1936), to stimulate CRF from the hypothalamus to produce more ACTH. ACTH then stimulates the release of adrenal glucocorticoids and mineralocorticoids to increase energy to combat the fatigue stressors, facilitate enzyme and suppress immune reactions. The suppression of immune reactions can lead to ascending amniochorionic-decidual infection. Infection, in turn, could lead to blunting of progestational effects as described above. Third, any one of several stressful factors leading to energy imbalance, hormonal and catecholamine release with subsequent change in uterine blood flow that can set in motion the various events leading to preterm parturition.

Conceptual Framework

The Modified Environmental Demands Fatigue Model is the organizing framework for this study and is presented in Figure 2.1. This framework depicts fatigue as the generalized, subjective perception of energy on a continuum from vitality to exhaustion (Lee et al., 1994) in response to stressors or demands. As energy reserves are depleted from internal (physiological and psychological) and external (situational) environmental demands, the individual perceives exhaustion. This results in a decreased

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Internal Environ- mental Demands		External Environ- mental Demands
Depression Anxiety Poor Sleeping Patterns Age Nutritional Status Weight Gain Smoking Alcohol Caffeine Exercise	Vitality ↑ → Fatigue ← ↓ Exhaustion	Marital Status Social Support Housing Occupational Conditions Rank Income Education Life Events Ethnicity
	€ Preterm Labor & Birth	

Figure 2.1: Modified Model of Environmental Demands

capacity for physical and mental work, catecholamine release, increase in uterine irritability due to change in uterine blood flow and preterm labor and birth.

This framework was empirically tested by Lee and associates (1994) and contains factors that can be assessed as possible elements of fatigue in military life. Physical illness and menstrual cycle phase from the original model were omitted as the study was limited to healthy pregnant women. Preterm birth, as the health outcome, was added to the Lee framework to serve as a consequence of exhaustion

Other nursing models (see Table 2.1) were considered prior to the selection of the Environmental Demands model. Criteria for selection of an appropriate model for this study included conceptualization of fatigue as (1) a normal condition rather than an

Table 2.1: Summary of Existing Nursing Fatigue Models

Hart & Freel	Levine	Piper	Potempa	Pugh & Milligan	Lee
x	x	x	x	x	x
		x	x	x	x
	x	x			
x		x			x
	x		x	x	
x	x	x	x	x	x
x	x	x	x	x	x
x	x		x	x	x *
x				x	
x		x	x	x	x
	x	x			
		x	x		
	Hart & Freel X X X X X X X X X X X	Hart & FreelLevinexxxxxxxxxxxxxxxxxxxxxxxxxx	Hart & FreelLevinePiperxx	Hart & FreelLevinePiperPotempaxx	Hart & FreelLevinePiperPotempaPugh & MilliganXX

* - Weakly shown on only one factor

effect of disease, 2) not limited to a side effect of medical treatment 3) part of a continuum rather than an all or none phenomenon, 4) a composite of physiological, psychological and situational antecedents, 5) primarily an acute (relieved by rest) rather than a chronic condition, and 6) empirically based.

Hart and Freel (1982) conceptualized fatigue as increased discomfort and decreased efficiency secondary to an energy reserve expenditure. They noted that chronic fatigue has a more psychic origin which may not accurately describe the fatigue experienced by severely exhausted pregnant women. Fatigue was also viewed on a continuum from local muscle to a generalized state of fatigue which, again, may more fit disease processes than pregnancy. Similarlly, Piper (1987) synthesized the literature to generate nursing theory regarding fatigue in cancer patients. The emphasis on certain treatments such as radiation, chemotherapy, interferon and altered neurotransmission makes this model less applicable to pregnant women. It was also tested on a sample of low risk pregnant women (Pitzer, 1991). Thirty-two percent of the items corresponding to the Piper fatigue model did not cluster, suggesting that the Piper model, appropriate for women with breast cancer, may meaningful related to the fatigue experience of pregnant women.

Schaefer (1986) used Myra Levine's Conservation model to develop a nursing fatigue model for another chronic illness, congestive heart failure. In this model, the individual interacts with three environments: operation (radiation, micro-organisms, pollutants), perceptual (light sound, chemical) and conceptual (language, ideas, symbols). Fatigue, in this model, is the manifestation of the body's attempt to heal itself which, again, implies an illness scenario with emphasis on the external environment as a source of fatigue.

Reeves and associates (1991) applied Potempa's nursing model of chronic fatigue (Potempa et al., 1986) to their study of fatigue in early pregnancy. The individual is seen as an open system affected by internal and external events as stimuli arise from peripheral working organs and then are sent to the reticular formation in the brain (Grandjean's fatigue theory). External environmental stimuli in this model play a larger role than the research in the area of pregnancy and fatigue indicates. Additionally, performance indicators are notably absent.

Finally, the Pugh and Milligan (1993) model was considered as a synthesis of available information on childbearing fatigue. Fatigue, in this model, is a consequence of physiologic, psychological and situational factors leading to decreased maternal performance. Situational factors include such variables as sleep, exercise and personal characteristics such as age that could be better placed under physiologic factors. This model, also, has the disadvantage of not having been empirically tested.

In the Environmental Demands model, fatigue is depicted as a normal condition rather than a result of a disease, not a side effect of a treatment, part of a continuum, appropriately classified physiological, psychological and situational antecedents, is more an acute than chronic condition and is based on empirical studies. With an addition of an outcome to the model and elimination of variables not related to healthy pregnant women, this model appears to best suit the considerations needed for analysis of factors contributing to a significant adverse outcome in pregnant military women. A word of caution regarding the empirical study results indicates that among non-pregnant civilian women, only depression, anxiety, poor sleeping patterns and negative life events were related to fatigue. This study tests the variables originally specified in the model and respecifies relevant variables for pregnant military women. The remainder of this literature review covers relevant research on the variables and relationships within this model.

Studies on Internal Environmental Demands

Internal environmental demands refer to psychologic and physiologic stressors which could cause an inbalance between energy resources and demands (Poole, 1986) during pregnancy. Pregnancy can be a psychological crisis (Colman & Colman, 1973) in which changes in body image and identity lead to energy-depleting behavior changes. Physiological changes lead to increased output of energy due to the 14 to 20 percent increase in oxygen consumption as a result of fetal development, cardiovascular and respiratory changes, and breast and uterine development (Poole, 1986) as well as fetal movement (Birkenfield et al., 1980). Progesterone, a hormone implicated in maintaining the pregnancy (Lockwood, 1994), is associated with a sedative effect in pregnancy, especially in the first trimester, with high amounts being secreted from the placenta (Blackburn & Loper, 1992). Pregnancy also alters serotonin metabolism and tryptophan, an essential amino acid, provides a vital pathway for this neurotransmitter that regulates sleep and energy metabolism (Kaplan, 1986).

Depression and Anxiety

Depression is the first of ten internal demand variables in the environmental demands model and has been examined in a number of studies of pregnant women. A sample of 70 married couples was included in a cross-sectional descriptive study

(Fawcett & York, 1986) investigating the type and frequency of physical and psychological symptoms experienced by pregnant (first and third trimester) and postpartal women and their spouses. The study was cross-sectional in that there were 20-23 couples who were chosen to participate at each time point, but they were not necessarily the same couples. All subjects were white, median age was 27.5 and 80% of the women had baccalaureate or higher degrees. The couples were asked to complete the Symptoms Checklist, a list of 20 physical and 3 psychological symptoms (depression, anxiety and feeling better than usual) and the Beck Depression Inventory (BDI) which contains "fatigability" as one of its 21 items. The most frequently reported physical symptom was fatigue (91% in early pregnancy; 100% in late pregnancy), and most reported psychological symptoms were anxiety (52% in early pregnancy, 71% in late pregnancy) and depression (43% in early pregnancy). Mild to moderate depression according to the BDI was found in 26% of the women in early pregnancy and 33% of the women in late pregnancy. Fatigability as a BDI item was the most frequently experienced symptom experienced by both spouses (14%). Unfortunately, since this was a descriptive study, no statistical analysis was made relating the Symptom Checklist to the BDI. However, it is important to note here that fatigue is frequently listed as a symptom of clinical depression which limits its comparison to depression as a separate entity.

A similar finding was noted in a prospective, longitudinal study (Affonso et al., 1990) of 202 married, largely white (76%) emotionally stable, middle-class, educated primigravidas, with an average age of 30. They were assessed for depression using National Institute of Mental Health's standardized clinical interview, the Schedule for Affective Disorders and Schizophrenia and Research Diagnostic Criteria (RDC) (criteria
for actual diagnosis of depression) at four times: first and third trimesters and at 1 to 2 weeks and 14 weeks postpartum. After accounting for pregnancy-postpartum symptoms, 8 symptoms, including fatigue, were higher among RDC identified depressed subjects. Eighty percent of the women reported severe fatigue symptoms in the first trimester which had decreased to 70% by the third trimester. Study investigators speculated on the hormonal connection between depression and fatigue which may leave the pregnant woman vulnerable to fatigue symptoms.

In another largely white, married, well educated population, Tunis and associates (1990) studied mood changes in 151 pregnant women undergoing chorionic villus sampling (CVS) and 30 women electing amniocentesis because of advanced maternal age. Mood was measured using the 6 subscales (fatigue, anger, confusion, tension or anxiety, depression, vigor) of the Profile of Mood States (POMS) at four times: enrollment for prenatal diagnosis, after CVS results were known (13 weeks), before amniocentesis results were known (18 weeks), and after all results were known (22 weeks). Repeated measures analysis of variance (ANOVA) revealed that anxiety, fatigue, and depression decreased as the pregnancy progressed with an increase at time 4 which was not statistically significant (except for depression in the amniocentesis group). This, again, showed a similar pattern between fatigue and anxiety and depression but, due to the purpose of this study which was comparing mood changes between two groups of women, the relationship between the two was not statistically analyzed.

The relationship between fatigue and depression, however, was analyzed in a study of fatigue in early pregnancy (Reeves et al., 1991). A convenience sample of 30 healthy women, 87% white, 90% married, age 20-35, enrolled at less than 20 weeks GA,

was administered the POMS, a Fatigue/Stamina Scale (Stamina was, interestingly, defined as a physical activity as well as a trait), BDI, a Sleep Behavior Questionnaire, a two item Nausea question as well as a semi-structured interview on fatigue, its time of onset, duration and factors which aggravated or alleviated it. There was concurrent validity between the fatigue subscales of the POMS and the Fatigue/Stamina scale (r=.79, p<.001). Ninety percent of the subjects reported feeling fatigued in the first trimester in the semi-structured interview (not clear if this was in the morning or evening). Pearson correlations were used to determine the relationships between environmental, psychological and physiologic variables with fatigue. Depression and anxiety were related to fatigue(r=.55, p <.01 and r=.38, p<.01, respectively). The results need to be viewed with caution as, again, the BDI, the instrument used to measure depression, contains fatigue as part of its operational definition.

Pugh and Milligan (1995) used the Center for Epidemiologic Studies Depression Scale (CES-D) to measure depression with emphasis on the affective component, and the Spielberger State-Trait Anxiety Index (STAI) to measure feelings of apprehension in response to situational stimuli in a longitudinal study of 11 pregnant women referred to earlier. The investigators used two measures of fatigue, the Modification of Symptoms Checklist (MFSC), a 30-item check list originally tested on industrial workers in Japan and the 18 item Visual Analog Scale for Fatigue (VAS-F) structured to address the multidimensionality of fatigue. Across time, fatigue measured on MFSC correlated consistently with state anxiety (r=.61, p<.05) in the second trimester to r=.76 (p<.01) in the third trimester). Depression also was correlated with fatigue from r=.67 (p<.01) in the second trimester to r=.84 (p<.01). The authors indicated that the relationships between the variables indicated a "cyclic" model where the variables enhanced one another. However, similar to the Lee study as noted below, this may have been due to collinearity of the variables. The small sample size prevented the use of regression analysis to partial out the contribution of anxiety and depression to fatigue.

Lee and associates (1994) also used the CES-D to measure depressive symptoms, the Lewis Anxiety Scale, the vitality subscale from the Depuy General Well-Being Scale and 90 day prospective diary for measuring fatigue. They found that severe fatigue was associated with depression and anxiety in 227 white, middle class, well-educated women. Only depression entered in the stepwise regression model, indicating the confounding nature of depression and anxiety. The advantage of using the CES-D for measuring depression was that it did not have items suggestive of fatigue or lack of energy. However, this study was not done on pregnant women.

In summary, the relation between the internal environmental demand variables of depression and anxiety and fatigue remains unclear. Along with methodological problems found in small convenience samples which were largely middle class white, fatigue is operationally defined as part of the symptom of depression in four of the studies reviewed and as a separate entity but not necessarily related to depression in another study. Hence, it would appear that fatigue may contribute to or result from emotional disorders. Fatigue may lead to increased anxiety with efforts to improve functioning, decreasing the time for rest. As fatigue increases, depression and other disorders may occur. One possible solution to this confusion would be to compare subscales of depression to fatigue on the POMS or the CES-D where depression is not operationally defined by fatigue. This still would not answer the question about order of causality but would reduce the amount of redundancy in the comparison of two constructs.

Sleep Disturbance

One of the functions most disturbed in pregnancy is sleep (Lee & DeJoseph, 1992). Compared with depression or fatigue, there is less of a problem with operational definition. This is because sleep disturbances refer more to the difficulties of initiating sleep, mid-sleep and early awakenings than with the subjective feeling of wanting to lie down and sleep which may be confused with fatigue. Also, sleep disturbances can be assessed more objectively from Sleep Efficiency Index (SEI), obtained by a standardized scoring system for sleep stages, using an electroencephalogram (EEG). The normal sleep cycle is characterized by non-rapid eye movement (NREM) sleep, designated in 4 numeric stages (3 or 4 known as slow-wave- sleep or SWS) followed by rapid eye movement (REM) sleep (Richardson, 1996). Previous studies (Karacan, 1968; Hertz et al. 1992) have shown an increased time of wakefulness after sleep onset, more sleep awakenings, more Stage 1 or 2 NREM, less REM sleep and decreased SWS in late pregnancy.

Reeves and associates (1991), in their study of 30 first trimester women, found that self-reported length of sleep did not correlate with fatigue (although it was not clear which fatigue measure--the POMS, Fatigue/Stamina or interview--was used for this analysis). In this sample, sleep did not effectively relieve fatigue despite the fact that getting more sleep was the most frequently identified strategy of women in dealing with fatigue. Moreover, there was a relationship between sleep disturbance scores and feeling tired upon awakening (r=.22) though not statistically significant with a sample of 30.

Again, the results of this study need to be viewed with caution due to small sample size and the fact that there was no report on the internal and external validity of the Sleep Behavior Instrument.

Types of sleep disturbances which could be related to fatigue in pregnancy are highlighted in a secondary analysis of employed women (Lee & DeJoseph, 1992). Data for the sample came from 760 women employed in seven hospitals on the West Coast of the U.S. Twenty-five pregnant and 29 postpartum women who worked at least 4 days a week and 32 hours a week were included in the analysis. The majority were white, married and ages ranged from 22-44 years. Sleep disturbance was measured by the General Sleep Disturbance Scale (GSDS). It consists of 21 items related to frequency in the past month of difficulty starting sleep, mid-sleep awakening and substances taken to induce sleep. Another 10 items were added to ascertain reasons for sleep disturbance. Fatigue, defined as a suboptimal function resulting from disturbed sleep was measured by a 100 mm visual analog line and questions on the GSDS asking about napping at work. Pregnant women experienced significantly more sleep disturbances in difficulty falling sleep (p=.007) and difficulty maintaining sleep (p=.01) due to frequent urination (p<.001) in comparison to postpartum women. Pregnant women were more tired at work, but the difference was not statistically significant. No conclusions could be made about the amount of sleep disturbance and fatigue. Like the Reeves study above, the results need to be viewed with caution due to the small sample size and the limitation of secondary analysis which limits the type of participants and type of employment.

In still another secondary analysis of a relatively small sample, Waters and Lee (1996) analyzed data collected in a descriptive, longitudinal study of 31 women during

preconception, pregnancy and postpartum. Sleep disturbances in this study were measured by a SEI gathered from polysomnography (EEG and electro-oculography) for two consecutive nights. Fatigue and vitality were measured by self-report prior to sleep onset and upon awakening with the VAS-F. The analysis compared primigravida and multigravida mothers as their sleep disturbance and fatigue changed between third trimester and postpartum. It was significant that, as the sleep efficiency decreased with the primigravida mothers at one month postpartum, their fatigue severity increased.

In a preliminary analysis of the same study of 18 women before, during and after pregnancy (Lee et al., 1994), there was a significant negative relationship (r=-.37) between fatigue severity and sleep efficiency in the third trimester. The strengths of this study included the objective measurement of sleep disturbance, a pre-pregnancy baseline to account for sleep disturbances and fatigue levels due to individual differences as opposed to those due to pregnancy, and triangulation with qualitative diaries.

The literature has shown conflicting relationships between sleep disturbances and fatigue during pregnancy. Small sample sizes, use of questionably valid instruments, and subjective reports of sleep problems have limited the power to determine relationships between these constructs. Sleep efficiency via EEG has shown a more definitive relationship between sleep disturbance and fatigue.

Age

There are a paucity of studies of age in relationship to fatigue in pregnancy and the results have been conflicting. In the Reeves study (1991), described above, which had an age range of 20-35, younger women experienced more fatigue (r= -.35, p<.05). Similarly, the preliminary analysis of 18 pregnant women, described by Lee and

associates (1994) indicated a statistically significant relationship between younger women and evening fatigue, particularly in the third trimester (r= -.48, p=.02).

In-depth interview data from 12 primigravidas, ranging in age from 35-44 years old, described how their professional schedules and a changing lifestyle from childlessness to becoming a parent was fatiguing (Winslow, 1987). The effect of chronological age and developmental tasks (planned change, control, transition and uncertainty) could not be assessed as interviews were not done with a younger, contrasting group of women.

In non-pregnant women, however, results have been more definitive. In a study of 223 recently hospitalized women (Wittenbborn & Buhler, 1979), women over 40 were more likely to be fatigued than at any other age (p=.02, controlling for depression). However, data from the first Health and Nutritional Examination Survey (HANES) (Chen,1986) indicated that there was not a significant difference in the percentages of older and younger non-pregnant subjects suffering from fatigue. Similarly, Lee and DeJoseph (1992) found no association between fatigue and age in 227 non-pregnant regularly menstruating women between the ages of 18 and 45.

In summary, results of studies of age and fatigue in women, pregnant and not pregnant, have been mixed. The small sample sizes in the pregnancy studies of age and fatigue limit generalizability to all pregnant women. Hormonal and other physiological changes in pregnancy limit generalizability from non-pregnant women but serve as an interesting contrast.

Nutritional Status and Proxy Variables

Despite claims that insufficient calories or inadequate nutrients may be a cause of fatigue (Kellum, 1985), studies of non-pregnant women have shown no connection

between caloric input and fatigue (Chen, 1985; Lee et al., 1994). In Chen's study, nutritional intake variables were based on respondent's 24-hour dietary recall while in Lee's study a Daily Sweets consumption scale and dietary patterns were used. Hence, with three entirely different methods of measuring caloric input, there was no statistically significant association with fatigue. Theoretically, energy reserves can be depleted under certain conditions such as failing to eat properly or failing to eat at the appropriate time (Lee et al., 1994). No studies reporting the results of dietary intake and fatigue in pregnancy were found.

However, studies of hemoglobin/hematocrit and weight gain as proxy indicators of nutritional adequacy have been done in pregnant women. Low hemoglobin and hematocrit (hemoglobin ≤ 10 gm/dl, hematocrit $\leq 30\%$) reflects inadequate dietary iron intake and poor iron stores (Luke et al., 1993). Deficient intake of iron is of concern because of its involvement in energy metabolism and physical performance (King, 1993). Inadequate weight gain during pregnancy is also considered largely related to nutritional deficiency due to poor dietary intake pattern (Abrams et al., 1989)

Pitzer (1991) measured the hemoglobin and hematocrit of 150 healthy women shortly after they took a self-report fatigue instrument. The Piper Fatigue Scale (PFS), a 72 item tool measuring timing, severity, emotional meaning and sensations of fatigue, was administered to 8 independent groups determined by length of gestation. The average group consisted of 18 subjects (range 12-20). Bivariate results showed that with lower hemoglobin/hematocrit, PFS total score was higher (r= -.57, p \leq .01). Stepwise regression controlling for potential confounders of fatigue was reported. Fathers' socioeconomic group (F= 8.51, p<.05) accounted for 5% of the variance in predicting temporal fatigue subscale (PFS) and history of pregnancy complications (F=5.03, p<.05) explained 2% of the variance of the total PFS. Hemoglobin/hematocrit did not enter the model. Power calculations for this study indicated an N of 240 was needed for statistical significance. The final sample was actually reduced to 138 due to missing data leading to reduced relationship between variables. The PFS was originally constructed to measure fatigue in cancer patients and, at 72 items, may have been too long for this population. Recording dietary intake or patterns, providing concurrent validity for this study, might have further strengthened the study.

In the Reeves study (1991), as described earlier, weight gain was negatively related to fatigue (r= -.34, p <.05). It should be noted that this study was done for first trimester women (<20 weeks gestation) and there is a possibility of confounding with nausea. Fatigue has been shown to be an important factor in nausea experiences of first trimester women (DiLorio et al., 1992; Van Lier, 1993) but no correlation has been documented between low weight gain secondary to nausea and fatigue.

Body Mass Index

If decreased weight gain due to poor eating habits or possibly nausea is associated with fatigue, what about body mass index (weight in kg/height in kg²) or BMI? Chen (1986) has indicated that in non-pregnant women, those above the median in BMI (>26) have 1.5 times the risk of being fatigued than those below the median. Lee and associates (1994) found no relationship between fatigue and increased body mass index (r= -.10). The implication here is that increased energy needed to move more body weight is found in late pregnancy (Lee & DeJoseph, 1992) or among heavier women. Hence, there is a possibility of a U-shaped relationship where deficient weight gain resulting in a low BMI and excessive weight gain resulting in a much higher BMI could be associated with fatigue. Luke and associates (1995) did measure weight gain and fatigue in their study of 1470 pregnant nurses, but unfortunately did not report an analysis of the relationship between BMI and fatigue. Comparing a "thin" BMI (<20) to a BMI of greater than 26 and the relationship to fatigue is another analysis that needs to be done.

Physical Activity or Exercise

Physical activity refers to exercise and other physical tasks in the Environmental Demands Model. This needs to be differentiated from physical activity that occurs on the job. In non-pregnant women, Chen (1986) has found that inactive subjects had more than twice the risk of fatigue than those who were active. Again, this was in agreement with the results of Lee and associates (1994) who found that vitality was associated with increased exercise (r=.199, p<.001).

In the only study examining discomforts of pregnancy and physical activity, Horns and associates (1996), examined 101 largely white, married, well-educated primigravidas, 48 sedentary and 53 active. A Physical Activity Index (PAI), a 12 item check list was developed to assessing active and sedentary exercise patterns. Women were asked to check those activities they did regularly for at least 15-30 minutes and the number of times each week. Women were classified as active if they performed an activity "sufficient" to stress the cardiovascular system as determined by a exercise physiologist. Fatigue was one of the items on a checklist of common discomforts of pregnancy. Ninety-one percent of the sedentary women chose fatigue as a common symptom compared to 73% of the active women ($\chi^2 = 4.22$) which was not statistically significant. Although the findings of this study support earlier studies of non-pregnant active and sedentary women, results should be interpreted with caution. Determination of level of activity was by self-report on a previously untested tool (no internal consistency reliability was reported). Fatigue was measured on a scale which inappropriately assumes that fatigue is an all-or-nothing event.

Substance Use: Tobacco, Alcohol, Caffeine

The final group of internal environmental demands related to fatigue has to do with substance use. Kellum (1986) noted that alcohol (a depressant) and caffeine (a stimulant) and decreased oxygenation from smoking may theoretically alter performance and energy levels. On the other hand, use of substances may help decrease stress levels which may indirectly decrease fatigue levels. Nelson (1994) describes smoking as part of the lifestyle of impoverishment in response to a highly stressful environment of crime and violence, poor housing and physically demanding and unrewarding jobs. Forgas and Meyer (1996) showed that stress and boredom, as opposed to easy accessibility, accounted for increases in smoking in Naval personnel during Desert Storm. The sample was only 4.6% female and not necessarily pregnant, but the study did document reasons for smoking in stressful military situations where the price of a package of cigarettes was much less than the civilian cost. Unfortunately, no measurement of energy levels of smoker and non-smoker sailors was done.

In non-pregnant women, Lee and associates (1994) showed no association between smoking behavior, caffeine intake and alcohol consumption with fatigue. In the Reeves study (1991) on first trimester women and fatigue, 87% of the sample were non-smokers and, with such small numbers, the relationship to fatigue was not reported.

Studies on External Environmental Demands

External Environmental Demands refer to the situational stressors which may be associated with inadequate energy reserves in the pregnant woman. These stressors refer to the cultural-based conditions that surround the woman, including family, shelter, job, socio-economic group, life changes and values and expectations of an ethnicity (as opposed to the genetic demands of a race) that tend to increase energy ouput.

Marital Status

Single marital status in pregnancy is often associated with lack of monetary and psychosocial support (Magann et al., 1995) which could theoretically be associated with fatigue. No one study has focused on marital status and fatigue in pregnancy, most studies examining other factors and fatigue have enrolled a largely married sample (Horns et al., 1996; Waters & Lee, 1996; Carty et al., 1996;Luke et al., 1995; Lee & DeJoseph, 1992; Reeves et al. 1991; Pitzer, 1986; Fawcett & York, 1985). In only one study (Pugh and Milligan,1995) were the participants mostly (63%) single. In the Pugh and Milligan longitudinal study, perceived fatigue using the MFSC and VAS-F, increased through pregnancy. Average daily VAS-F scores for the 11 mostly multiparous, low income women in the study ranged from 46.7 \pm 13.2 in the first trimester to a high of 51.5 \pm 16.9 in the third trimester. In a comparable longitudinal study (Waters & Lee, 1996) with most of the women married, average VAS-F evening fatigue score in the third trimester was 64.79 \pm 19.27 for the for 19 multiparous, middle class women in the study. This is indicative of higher evening fatigue in the married group but, unfortunately, it is not clear if Pugh and Milligan measured VAS-F in the day or evening. If we are comparing two evening scores, it is also possibly erroneous to assume that the institution of marriage, in itself, implies positive financial and psychosocial support and less expenditure of energy during pregnancy.

Social Support

The construct of social support implies much more than maintenance of a socially sanctioned relationship. This study used House's (1981) conceptualization of social support which is defined as interpersonal transactions which involve one or more of the following categories of behavior: 1) emotion concern (empathy, love, liking), 2) instrumental aid (goods and services), 3) information (about the environment) and 4) appraisal (information relevant to self-evaluation). Emotional concern fosters feelings of being loved and part of the group which permits people confidence to change themselves to meet environmental demands that are energy depleting. Instrumental support would directly affect situational stressors by direct modification of the environment such as providing money, labor, or time. Simply feeling secure (Gottlieb, 1985) that help would be available if needed would reduce a person's anxiety related to demands made of them. Information support may reduce energy expenditure by helping people perceive a situation as more manageable. A decrease in emotional distress and positive health behaviors could result from such information (eg. awareness of nutritious foods, how to prevent preterm birth). Appraisal support from family, friends or partner (social network) could impart rationale for positive health behaviors and instill confidence against energy depleting demands. In sum, social support can instill in the pregnant woman confidence

to meet environmental stressors due to security from emotional concern of others and knowledge that material, informational or evaluative help is available if needed. Social support, hence, serves as a "buffering" mechanism against stress.

There is now a substantial body of literature accumulated to demonstrate that social support in general is a crucial variable in understanding of health and illness (Broadhead et al., 1983). More specific to pregnancy, evidence is available that social support may positively influence health outcomes (Norbeck & Tilden, 1983; Nuckolls, Cassel, & Kaplan, 1972, Norbeck et al., 1996). There are no studies on social support in pregnant women which focused on association with fatigue.

Lee and associates (1994) studied social support and other variables related to fatigue with 262 non-pregnant women (details described earlier). Social support was assessed using the Inventory of Socially Supportive Behaviors (Barrera, 1981). This tool asked participants about social support in their lives as defined by House (emotional concern, instrument, informational and appraisal support) and about those with whom they had unpleasant encounters (conflicted support). Only conflicted social support was weakly related to fatigue (r=.11, p=.046).

Brown (1987) compared employed and non-employed pregnant women regarding their experience of health and social support during their pregnancies. Three hundred thirteen largely white, married, middle class women responded to a questionnaire (51% responded via mail). The 135 item Support Behaviors Inventory (SBI) was used to measure social support. Half of the items made specific reference to pregnancy and the other half applied to any population with 45 items referring to the partner, 45 referring to other people in the woman's life (excluding partner) and 45 referring to importance of these behaviors to the participants. The 50 item health responses questionnaire asked subjects about symptoms they experienced since the beginning of pregnancy (which were later divided into 3 dimensions of health: somatic, psychological and behaviorial and well-being. Fatigue was one of the symptoms (point biserial correlation =.17, p<.001) that most discriminated employed pregnant women from homemakers. Although there was no report in the study about the direct relation between fatigue symptoms and social support, employed women received a greater percentage of their overall support from their social network and were more satisfied with their support than were homemakers. Although they were more fatigued, employed women appeared to have greater competency skills or increased inclination to seek other's support.

Housing

Housing refers to non-occupational work environmental conditions. The home environment can be stressful when it is crowded, poorly maintained, lacking in esthetics and isolated from central resources (Pesznecker, 1984). Hence, a military barracks situation with its lack of privacy and lack of esthetics may approach a fatiguing situation (Magann et al., 1989). Hickey and colleagues (1995) described a strenuous home environment for pregnant women using 10 activities: (1) number of children in the household, (2) number of preschool children cared for, (3) carrying or lifting small children, (4) regularly carrying loads weighing more than 20 pounds, (5) number of hours standing per day, (6) number of hours walking per day, (7) climbing stairs, (8) doing strenuous inside chores, (9) doing strenuous outside chores, and (10) doing strenuous recreational activity. High "fatigue" was defined as a score of greater than 4 on a 10 point scale from 0 (low) to 10 (high). This scale was administered to 401 low income women at 24-26 weeks GA in a prospective contextual examination of stress and preterm delivery. Unfortunately, there were no measurements for fatigue severity. The authors referred to the home activity scale total as the "fatigue index," but this scale, as defined above, did not actually measure fatigue as a subjective measure of energy level perception.

Other investigators have used single variables such number of children to describe the home situation. In the Reeves (1991) study of 30 women of less than 20 weeks GA, number of children was not statistically related (r=-.22) to fatigue. In a group of 227 non-pregnant women, Lee and associates (1994) reported that time spent parenting was significantly related to fatigue (r=.13, p=.015).

Income, Education, Military Rank

Socio-economic variables include income (total amount of money made by the family in one year), education (numbers of formal education) and rank or occupational status (defined by prestige, income and educational standards). An inverse relationship between income and health has been well-documented (Nelson, 1994) with income, education and occupational status as the most commonly used indicators of socio-economic status.

Income, as a measure of socio-economic status, is less stable over time, and family size and cost of living need to be considered. The effect of education is less useful in certain populations, such as women, due to the increasing homogeneity of educational levels. For instance, Norbeck (1984) recruited 32 single mothers who were in the low income bracket but most had 13-16 years of education (a middle class standing). If only education was listed, the women would have been misclassified. Nevertheless, education is considered to have an impact on health by its influence on life-style behaviors, problem solving ability and values, qualities not totally dependent on economic resources (Liberatos et al., 1988). Military rank as an occupational status has overcome some of the gender and ethnic biases found with occupational scores in civilian studies (James et al., 1987).

Explanations for the link between poor health and low socio-economic status include (1) decreased access to care due to lack of health insurance and (2) a life style associated with increased risk factors such as obesity, decreased physical activity and uncontrolled high blood pressure (Nelson, 1994). Health promotive behaviors increase with the standard of living (Palank, 1991).. All of these factors contribute to a tremendous amount of psychosocial stress which may deplete the energy resources of those who have to deal with them. However, for a military sample, the other links between poor health and low socio-economic status are not considered problems. This is because of the excellent access to medical care through free health insurance and an emphasis on physical fitness (Magann et al., 1995).

Although there are no specific studies focusing on the socio-economic variables (income, education or rank) and fatigue in pregnant women, it is instructive to compare studies which examined fatigue levels of largely middle income pregnant women to studies with low income women. Contrary to what economic impoverishment theory would predict, the evening VAS-F mean scores in the third trimester of 19 middle class pregnant women in the study of sleep efficiency (Waters & Lee, 1996) described earlier were higher than the third trimester scores of 11 low income pregnant women (Pugh & Milligan, 1995). Socio-economic status was indicated only by educational level (93% had college education) in the Waters and Lee (1996) study and by education (81% had a twelth grade education or less) and "low income" (54%) in the Pugh and Milligan (1995) study. Lack of more precise definition of socio-economic level, lack of clarity of time of day of fatigue measurement, and small sample sizes probably decreased the accuracy of these studies in terms of predicting fatigue levels. Larger studies (with sample sizes of 400-1470) have been done with low income (Hickey et al., 1995) and middle class pregnant women (Luke et al., 1995) but differences in the scoring of the fatigue instruments and study designs (prospective and case-control, respectively) also precluded a valid comparison.

Occupational Conditions

Conditions in the workplace have been studied extensively as a source of stress, though not necessarily fatigue, in pregnant women. In the 1950's, a job was considered a source of stress if the pregnant woman worked outside the house beyond 28 weeks GA (Douglas, 1950; Stewart, 1955). Job titles and job conditions were not reported. Later, job titles were analyzed by a dictionary of occupational titles or similar source to determine environmental exposures by job categorization (Peoples-Sheps et al., 1991). Job misclassification was a strong possibility.

An Occupational Fatigue Index (OFI), developed by Mamelle and colleagues (1984) quantified the degree of "fatigue" linked to working conditions of women in two towns in France. The five major sources of occupational fatigue were: 1) posture (standing for more than 3 hours per day), 2) work on industrial machine (work on assembly line, deal with machinery vibrations), 3) physical exertion (engage in strenuous physical activity; carry load of more than 20 pounds), 4) mental stress (do repetitive tasks; work is boring) and 5) environment (work with chemicals, significant noise, temperature or moisture level). Although presence or absence of sources of fatigue were measured, no actual level of severity of fatigue was noted in the formation of the OFI (Mamelle et al., 1984) or in most subsequent studies using the OFI (McDonald et al., 1988; Teitelman et al., 1990).

In only one study was perception of severity of fatigue compared with the OFI in a study of pregnant women. Luke and associates (1995) enrolled 1470 nurses who were asked about a pregnancy during which they worked as a nurse during the preceding 10 years. The participants were given a 46-item questionnaire designed to measure sociodemographic information, lifestyle, working conditions as measured by a modified OFI, hours worked per week and shift and a one item measure of fatigue-a single question about tiredness at the end of a shift. Severe occupational fatigue on the OFI was defined as a score of 3 or 4 of a possible 4. Sixty-eight percent of the nurses who experienced severe fatigue stated that they were extremely fatigued at the end of a typical shift. The investigators noted that this finding adequately validated the OFI as a measurement of fatigue. Methodological concerns included the retrospective nature of this study with the high risk of recall bias, validation with a relatively imprecise, unstable measure of fatigue (single question) and the modification of the OFI (rewording of two categories and complete removal of another) without a pilot study for psychometric retesting.

Portions of the OFI (standing, lifting weights) were compared with presence or absence of "extreme fatigue" in a follow-up study of 2,447 women who had been part of a larger study (n=50612) of effects of work on the fetus (Cherry, 1987). Criteria for inclusion included employment after the twenty-seventh week of pregnancy, a first pregnancy and delivery of a term infant with no apparent abnormality. A questionnaire was sent to each woman in the sample at three months postpartum to elicit information on job demands and health complaints during each trimester of pregnancy and for the period 12 months before pregnancy and at the time of completion of the questionnaire. Fatigue (analysis was only available for the third trimester) was related to standing with back bent forwards and lifting weights and twisting (p<.001). Logit analysis was done to test whether each of these demands made an independent contribution toward report of symptoms. Lifting weights did not make an additional independent contribution toward fatigue. Generalizability of this study is limited by the retrospective, non-experimental design (recall as well as different kinds of work), inclusion of only women with a normal birth outcome (may have underestimated the way job demands affect the health of pregnant workers) and those who worked beyond 28 weeks (those who guit earlier may have had more demanding jobs). The measurement of fatigue was also a limitation in this study as it was a part of checklist of symptoms, and, like the Luke study described above, it was a one-item measure of the construct.

Occupational conditions in pregnancy have been placed in indices measuring occupational fatigue but have not been adequately compared to measurement of fatigue severity. Most of the studies have been retrospective and fatigue measurement tools have been either part of checklists or operationalized as an all-or-nothing event.

Life Events

Energy reserves can be further depleted by numerous life events. Although no causal link has been established, life event measures have provided a measure of exploring the link between psychosocial stressors and physical dysfunction. Life event changes represent the woman's social environment and (1) vary with the personal importance of the pregnancy to the woman (Berkowitz & Kasl., 1983), (2) increase the woman's anxiety and the resulting catecholamine release increases uterine contractions in the so-called accumulation hypothesis (Omer & Everly, 1988), and (3) vary with the kind of social support provided (Norbeck & Tilden, 1983).

Norbeck (1984) modified a Life Event Questionnaire (LEQ) for women. After interviewing 32 low income, non-pregnant women about life event changes in pregnancy as a basis of content for the LEQ, two samples (60 graduate students and 69 low income women) took the revised tool and, for concurrent validation, the STAI, POMS and the Brief Symptom Inventory (BSI), a 53 item scale measuring global distress. The revised LEQ contained 82 events. For the LEQ, the participants were instructed to determine whether an event was good or bad for them. Then they needed to indicate on a 4-point scale the impact this event had on her life, from "no effect" to "great effect" (scored 0 to 3). For the 60 female graduate students, negative event score correlated significantly with fatigue subscale of the POMS (r=.54, p<.001) as well as the LEQ total events score (r=.48, p<.001). No fatigue scores were reported for comparison on the revised LEQ for the low income group.

In another study of non-pregnant women, Lee and associates (1994) did a secondary analysis of 227 women who took the Life Events Questionnaire modified by Norbeck just described above. As in the Norbeck study, the Negative Life Events score was significantly associated with fatigue (p=.002) vitality was associated with the Positive Life Events score (r=.178, p=.004).

Fagley and associates (1982) enrolled a convenience sample of 1306 women between 3 and 9 months GA who were attending prenatal classes from seven Utah hospitals. In this cross-sectional study (there were women enrolled at each month from 3-9 months GA, with a minimum of 53 women at 3 months GA to a maximum 378 women at 7 months GA), participants were given the Symptom Proneness (SP) scale which measured symptoms or illness in the last 10 years, the Cornell Psychiatric Items (CPI) which measured psychologic upset, two stress measures (STRESS) used to measure life change 0-6 months ago (STRESS) and 6-12 months ago (STRESS2) and the General Adaptational Distress (GAD) Scale which includes symptoms of the stress reaction, including fatigue. It was found that SP needed to be considered along with STRESS (life changes) and CPI to predict fatigue. CPI was most predictive of fatigue symptoms from 3 months GA [F=19.802 (1,49), p<.01] to 8 months GA [F=53.136 (1, 252), p<.01] while SP and STRESS were more predictive at 9 months GA ([F=5.584,(1,64), p<.05]. The investigators suggested that as the physiological load of pregnancy increases past the seventh month, the adaptive range of resiliency decreases and leads to distressful symptoms. Limitations of this study include its cross-sectional design where inferences about the results depend on the equivalency of the women in the different months of pregnancy. Also two of the measures (STRESS2 measuring life changes 6-12 months ago and SP measuring symptom proneness) were retrospective. STRESS measuring life changes 0-6 months ago was more predictive of GAD. GAD was also more a measure of sleep disturbance and environmental sensitivity but did contain 2 items on persistent tiredness and decreased energy. Also the convenience method of sample decreased generalizability to other populations, as over 50% had some college education and over 90% were married.

Ethnicity

Ethnicity, defined as the values, beliefs and subsequent behaviors associated with certain groups of individuals, has been confounded in many studies with the socioeconomic variables of education, income and occupational status (Lieberman et al., 1987). Hence, it would be instructive to examine outcomes when aspects of socioeconomic status are controlled. In a study where all participants (African-American and White pregnant women) were college educated (Schoendorf et al., 1992), other factors such as insufficient access to care [Odds Ratio (OR) = 1.38,95% Confidence Interval (CI)=1.26-1.51], a factor related to income, made a difference in poor health outcome. Higher parity of African-American women, possibly a cultural value, was associated with a 23 % increase in the risk of infant mortality. But, when parity was controlled in a logistic regression analysis, there were still large differences (OR = 1.82, 95% CI = 1.64-2.01] between outcomes of African-American and White infants. In a study of Kaiser patients (Shiono et al., 1986) where nearly all participants were of middle class status, after controlling for the effects of 22 factors, the odds ratios for another pregnancy outcome and low birth weight (LBW) still indicated a difference between ethnic groups (African Americans, 2.41; Asians, 1.37; Hispanics, 1.25). Finally, where access to health care is equalized such as in military populations, negative outcomes for Whites tend to be higher and African American rates tend to be lower than in the general population (Adams et al., 1993; Kugler et al., 1990). Negative outcomes for African American women, however, were still higher than for white women. Hence, there are other factors

related to ethnicity such as racism which limits access to quality, dignified care (Murrell, et al., 1996) and influences health outcomes.

Although no studies have examined ethnicity and fatigue severity, the cultural context of ethnic groups may explain differences in energy levels as part of a measure of health (Rowley et al., 1993). Theoretically, ethnicity may be a surrogate for social environmental factors. Culturally-based family centered practices (Burk et al., 1995), for example, may account for difference between African Americans and Hispanics as both groups have similar socio-economic standing but different health outcomes. There may be differential exposure of African Americans and Whites to stress such as chronic strains, remote traumatic stressors or exposure to stressors specifically related to racism (McLean et al., 1993). Similarly, the nature of social support in different cultures may increase energy expenditure in different cultures (Shiono, et al, 1986). Hogue and Hargraves (1995) point out that persons in stressful situations may require higher levels of certain nutrients in order to manage neuroendocrine and immunologic responses to stress. Traditional prenatal care may also be insufficient to offset the chronic strain felt by African American women (Graham et al., 1992). Social support, generally thought to be a buffer against stress in a small sample of White women (Nuckolls et al., 1972), can occur in certain forms that may be detrimental in other samples (Oakley, 1985). Therefore, in studying ethnicity and the perception of fatigue, the social forces, including the childhood environment of the mother (Emanuel, Hale & Berg, 1989) that create stressors, and the cultural responses that are utilized (seeking protection through social network or via certain healthful or unhealthful behaviors) for handling environmental threats, need to be better understood.

Perception of Fatigue as a Symptom Experience

According to the Symptom Management Model [University of California, San Francisco (UCSF) Faculty, 1994], perception is the "conscious, cognitive interpretation of information gathered by the senses in the context of a particular environment or situation" (p. 273) while variables are factors which influence this perception. As an adaptation of the Symptom Management Model, the Environmental Demands Model focuses on the person variables (psychological and physiological), environmental variables (physical, social and cultural) and health/illness variables (risk factors or substance use) which influence the perception of a symptom. The individual, in this case, the pregnant woman, evaluates the information from her environment and responds with changes in mood or role performance to reflect her energy level.

The literature review of how theoretically relevant variables affect fatigue shows conflicting results. This was largely due to methodological problems such as inadequate tools (eg. contain fatigue as one of the factors, or contain one question asking about fatigue as an all-or-nothing event), small sample sizes, or retrospective designs. Consequently, the pregnant woman who perceives and responds to fatigue is portrayed as a possibly depressed, anxious, sleep disturbed (via EEG), anemic, sedentary woman with low weight gain in the first trimester, high prepregnant BMI, demanding working conditions, experiencing negative life events. In non-pregnant women, there were conflicting results with fatigue and dietary intake depending on how intake was measured. In pregnant women, contrary to what would be theoretically predicted, there were trends of fatigue association with young age, being married, middle class status, high social support, and with no association with children in the home. However, with non-pregnant women, conflicted support and parenting children correlated with fatigue severity. Finally, there were no studies where substance use and ethnicity were associated with fatigue. With a more rigorous research design in a sample with demanding working conditions, where valid and reliable measures of fatigue are compared with the various theoretically relevant variables of the Environmental Demands Model, it remains to be seen whether these relationships are statistically supported.

Studies of Preterm Labor and Birth as a Consequence of Fatigue

In this section, studies that link the fatigue to preterm labor and birth portion of the Environmental Demands Model are examined. Fatigue as a symptom in measurement tools such as risk scoring instruments for preterm birth will first be analyzed followed by a historical review of occupational fatigue activity studies used as proxy variables for fatigue.

A symptom outcome refers to consequences associated with the symptom experience (UCSF Faculty, 1994). Symptom outcomes can vary from self-care ability, financial status, quality of life, functional status to mortality and morbidity. In the Environmental Demands Model, the consequence of the fatigue perception, which is influenced by a number of internal and external environmental demands, is perinatal morbidity which is, in this case, operationalized as preterm labor and delivery. The literature review of physiological mechanisms revealed a biologically plausible link between fatigue and preterm labor and preterm birth.

However, there has only been one study examining fatigue severity with preterm birth. Pitzer and associates, as a follow-up of a study examining fatigue, hemoglobin/hematocrit and pregnancy outcome (1994), examined 40 "at risk" women and 40 "low risk" women for fatigue, hemoglobin and hematocrit, and preterm birth. The "at risk" group was selected based on at least one of the following factors: previous preterm birth, diethylstilbestrol (DES) daughter, cone biopsy, incompetent cervix, and cervical changes. The "low risk" group had no risk factors for preterm birth. Subjects were matched by age, race, week GA, level of education and parity. Both groups were given the PFS and had their blood drawn for hemoglobin and hematocrit. Greater fatigue (p=.03) and lower hemoglobin/hematocrit (p<.0001) and more preterm births (n=9, 22%) were found with the "at risk" group than the "low risk" group (n=1, .03%). Despite matching, education and income were still lower for the "high risk" group (no statistics mentioned). Unfortunately, the aim of this study was only descriptive, not predictive. It confirmed that fatigue should be part of the "high risk" assessment of pregnant women.

For a number of years now, "fatigue" has been inbedded in risk assessment systems used to identify high risk women who have the increased likelihood of delivering before 37 weeks GA. Most of the risk scoring systems have divided these factors into demographic risks, behavioral risks, previous medical and obstetrical conditions and current pregnancy problem (Main, 1988). Each factor is given a weight or a value and then summed. Fatigue usually has been a lower weighted score such as 1 or 2 compared to a factor like multiple gestation with a score of 10 which has increased odds of predicting prematurity. Generally the higher the score, the more likely the woman will experience an adverse pregnancy outcome. A cut-point, based on clinical experience, is used to divide women at high risk or low risk for an unfavorable outcome.

The value of these risk scoring systems is based on their ability to predict pregnancy outcome. Sensitivity is the percentage of women delivering preterm infants who were accurately defined as being high risk whereas specificity is the percentage of women delivering term infants who were correctly defined as being not high risk. These measures are derived by comparing the results of risk scoring with the actual birth results. The actual proportion of high risk women who deliver a preterm infant is the positive predictive value of the risk scoring tool while the relative risk is the ability of the risk to differentiate preterm birth among low and high risk women [eg. a relative risk (RR) of 1.0 indicates a similar rate of preterm birth among high and low risk women].

Table 2.2 contains the performance statistics for the risk scoring tools containing fatigue associated factors. Most of these tools have been based on the system initially described by Papiernik and associates (1974). The most successful risk scoring attempt was developed by Creasy and associates in 1980 on 966 pregnant middle class women in New Zealand whose preterm delivery rate was 6.1%. At a cut-point of 10 on a modified Papiernik scale, 12.9% were identified as high risk. The sensitivity of the tool was 64% with even a higher sensitivity of 77% if only multiparas were considered. The positive predictive value was 30%--over one third of women defined as high risk actually went on to deliver preterm infants. The women were re-evaluated at 26-28 weeks gestation which increased the accuracy of the predictions (Creasy et al., 1980). On the other hand, Main and associates in 1987 had the least successful attempt at risk scoring on a population of low income inner city African American women in Philadelphia. With the same cutpoint as Creasy, 36% of the women were identified as high risk which was done only one time on enrollment into prenatal care. But the sensitivity was a low 28% with a positive predictive value of only 18% and relative risk of 1.0. Main and associates tried to improve the system by applying multivariable analysis and adding 60 more risk factors,

Study	Sample Size	% Preterm	[%] High risk	Sensitivity	Specificity	Positive Pred Value	Relative Risk
Kaminski et al, 1973	4008	8.1	14	30	87.0	16.8	2.5
Fedrick, 1976	283	16.7 (Preterm labor)	17	Primipara: 9 Multipara: 25		Primipara: 33 Multipara: 22	
Creasy et al, 1980	966	6.1	12.9	64.4	90.4	30.4	12.2
Herron et al, 1982	1422	2.4	15	56	87	18.0	
Mc Gregor et al, 1990	202	4.5		66.7			2.6
Main et al, 1987	391	14.8	221	20.55	79	18	1.0
Mueller-Heubach & Guzick, 1988	4490	8.8	17	38.5	85.6	13.3	3.1
Holbrook et al, 1989	7329	5.3	15.8	39.9	85.6	13.3	3.5
Owen et al, 1990	7478	8.5	15	29	89.6	16	
Taren & Graves, 1991	9014	8.4	15	26	86	15.9	

ACCURACY OF RISK SCORING SYSTEMS DESIGNED TO PREDICT PRETERM BIRTH (USING PAPIERNIK BASED SCALE) TABLE 2.2

including some fatigue related factors, work outside the home and number of children at home, but was unable to distinguish between high and low risk women (Main et al., 1987). The poor performance of this attempt at risk scoring was attributed to the modified Papiernik tool being better able to distinguish between social classes as opposed to other risk factors related to preterm birth. Since the Papiernik tool contains items such as "work outside the home" and "unusual fatigue," it may be true that lower socio-economic status women may need to work outside the home to earn more income for the family and experience unusual fatigue as their lower paying jobs may require more physical exertion.

There are other limitations to risk scoring tools. Many risk scoring systems are much better at predicting preterm delivery in multiparous mothers (Creasy et al, 1980). Ross and associates (1986), for instance, found the sensitivity of their system to be 1.4 times better for multiparous women. It was 4.5 times better for multigravid women in the study of Mueller-Heubach and Guzick (1988). Many of the systems have a "historic" bias as there is a heavy reliance on historical information--especially previous preterm births. The problem is that historical factors are not modifiable. For predictive factors to serve as identifiers for preventive action, they need to be changeable. Fatigue related factors qualify as modifiable risk factors. But since they play such a relatively minor role in risk scoring tools, this decreases the sensitivity of these measures and relevance to the daily habits of pregnant women.

Another limitation is the "treatment paradox," an idiosyncrasy of risk scoring, where treatment is rendered to identified high risk mothers (eg. providing rest periods for fatigued mothers), thereby lowering their risk of delivering preterm (Strobino, 1993).

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This lowers the effectiveness of the risk scoring system by decreasing positive predictive value and relative risk, especially if nothing special is done with the low risk group.

Finally, a major limitation is that the factors that are listed in the risk scoring systems are often poorly defined. Papiernik's tool, for instance, was derived from a study of 153 mothers of prematures and 222 controls at a single examination at 32 weeks. Four factors of fatigue were listed: work outside the home, strenuous work, an apartment above the third floor without elevator and long daily commuting time (more than 1 1/2 hours daily). Strenuous work was defined as:

"strenuous physical effort, standing, or continuous nervous tension. Occupations for women such as nurses, telephone operators, punch-card operators, cleaning staff, sales staff, hairdressers, dentists are implied"

(Papiernik et al., 1974, p. 31).

A tool is only as good as the studies from which it was derived and tested. If the studies have methodological errors, such as not accounting for confounding variables, then this renders the risk factors identified on tools as less useful for clinical assessment. Papiernik's study was prospective and accounted for confounding variables. However, the fact that "strenuous" was defined as "strenuous physical effort" rather than perception of fatigue severity probably influenced subsequent research on fatigue and preterm birth. However, "work" or sources of work fatigue without any further qualification has often been listed in the epidemiologic literature as synonymous with fatigue severity.

Early Studies

Early studies in Britain focused on the length of work during pregnancy as contributing to prematurity. In a study (Douglas, 1950) done in 1946 by the Royal College of Obstetricians and Gynecologists on 13257 married primigravidas, researchers found a significantly higher prematurity rate in primigravidas who worked late in pregnancy. This was done from a case control design where each premature infant was matched with a mature one for sex, birth order, social class, overcrowding, mother's age, and geographic region. A subsequent study by Stewart (1955) showed that 1318 women working beyond 28 weeks in their pregnancies had a 2.5 times greater risk of delivering a premature infant. This was a retrospective cross-sectional study which involved examination of records for variables associated with pregnancy outcome. Along with employment, low socio-economic class and single marital status were related to prematurity. The problem with these early studies is that only Chi square statistical analysis was done and, consequently, the relationships between the independent variables were not indicated. Also low birthweight (<2500 g) was the definition of prematurity due to the poor gestational age dating techniques at the time. The low birthweight definition may either encompass the risk of shortened gestation and growth retardation of fetuses, rendering these studies difficult to compare with later ones where this definition is clearer.

A case control study in Scotland, conducted at about the same as the studies above, showed no difference between cases and control in prematurity rate (Illsley et al., 1954). There was matching for social class, height, age, timing of marriage in relation to conception, type of work done during and before pregnancy and exclusion of those with premature rupture of membranes (PROM), fetal anomalies and chronic illness. Amount of prenatal care, domestic responsibilities and the nature of the housing conditions among the 206 participants was described. The investigators attempted to increase the contrast between the two groups by comparing the infants below 5 1/2 pounds (n=103) with those matched controls between 6 1/2 and 8 1/2 pounds (n=103). Those infants between 5 1/2 and 6 1/2 were thought to be too close to premature size and those over 8 1/2 were excluded due to a possibility of abnormality in mother or child (eg. diabetes). The relatively smaller number of subjects in this study may have reduced the effect of the independent variable. With a larger case control study (n=903), Drillien (1957) also found no difference between women with premature infants employed greater than 6 months compared with term infants. Similar variables were controlled. Interestingly, social status of the pregnant woman in her childhood was considered an indicator of the woman's environment in childhood and early adulthood and was considered a more important factor than present employment (t = 4.52, p <.0001).

Prospective Studies and Job Titles

All of the studies reviewed up to this point were conducted retrospectively and had the possibility of recall bias. They contained no description of the woman's work except whether work was inside or outside the home. In contrast to these investigations, Tafari, Naeye and Gobefzie (1980) conducted a prospective cohort study of Ethiopian women. Women between 20 and 24 weeks and 36 to 38 weeks gestation were surveyed regarding their physical activity and food intake. Hard physical labor included whether she carried jars of water long distances and ground grain with no domestic help, or did strenuous work outside the home. Physical activity was considered light when the housewife had domestic help or when the woman had a sedentary job outside the home. The study excluded women with significant confounding variables (anemia, bacteruria, edema, proteinuria, diastolic blood pressure >85 mm Hg, positive history of syphilis, history of preterm delivery, twins, >10 cigarettes per day, "unstable" marriage and unwanted pregnancy) related to low birthweight. Women who engaged in hard physical labor and had lower calorie intake had significantly lighter newborns. Due to the many variables excluded in the design, generalizability is limited to socially and physically low risk women in underdeveloped countries.

The Collaborative Perinatal Project (Naeye & Peters, 1982), conducted in 12 different regions of the United States between 1959 to 1966 but analyzed after the Tafari study, examined how pregnancy outcome was altered with more precise descriptions of work. This was also a prospective cohort study consisting of a much larger sample of 7722 women divided into three groups: those who did not work outside home, those who had work requiring sitting and those who had employment requiring standing. Naeye was not able to establish the connection between type of work and shortened gestations with women who worked into the third trimester but was able to demonstrate newborn infants weighing 150 to 400 grams less along with placental infarctions in mothers who were engaged in standing types of employment. The growth retardation finding remained after the data were stratified by race, socioeconomic status, age, pre-gravid body weight, number of children at home, smoking habits and blood pressure. The results of this study were strengthened by the fact that it was the first of the employment and pregnancy studies that used multivariate statistics to determine if confounding variables affected the relationship between outside employment and fetal growth. Most of the subsequent studies used these more powerful and appropriate statistics. Nevertheless, the data were nearly 16 years old by the time they were published.

Furthermore, Naeye's findings have not been replicated by others using somewhat different classification schemes. Meyer and Daling (1985) conducted a case control study of 5822 mothers of infants with low birthweight determined from birth certificates in the state of Washington. Based on job title, women were classified as housewife, mixed (25-75% sitting or standing), standing (75% of the time), and active (active or strenuous work >25% of the time). There was no relationship between activity group and low birthweight infant even with stratification of maternal characteristics. Zuckerman and associates (1986) obtained the same result in a cross-sectional study done in the postpartum period with a different set of categories. These included: housewife, paid employment outside home in the third trimester in standing position and women who performed work in sitting or standing position in first and second trimester.

More Recent Composite and Job Title Studies

In more recent studies, Teitelman and associates (1990) collected data on a prospective cohort of 1206 employed women who were interviewed in the first and second trimesters. The investigators divided the sample into three categories: 1) standing - jobs which required standing greater than 3 hours per day, 2) active -jobs requiring continuous or intermittent walking and 3) sedentary - jobs which requiring less than 1 hour standing or walking. The rate of preterm births was highest in standing group (7.7%) compared to sedentary (4.2%) and active (2.8%) group. Relative risk was 2.85 (95% CI= 1.34-6.00) for the standing group. Similarly, Ramirez and colleagues (1990) also found a significant difference between preterm birth and physical demand assessment in active duty military women whose jobs were classified into specialties

based on upper body strength. Relative risk for preterm birth increased from 1.4 for the medium demand category to 1.8 for the heavy demand category.

It is obvious that these studies on employment job title and preterm birth/low birthweight are not consistent. In the latter studies (Teitelman et al, 1990; Ramirez et al., 1990), however, the fact that employed women were not compared to housewives increased the effect of strenuous activity of the job. In the other studies, housewives were used as a control group. It has been shown in a number of studies that women with employment outside the home are more apt to have a lower preterm birth rate than housewives (Marbury, 1984; Murphy, 1984; Mamelle, 1984). One possible explanation is the *healthy worker effect* where women who work are physically healthy enough to be in the workforce, and tend not only to enjoy the benefits of extra income, but also have better health insurance, facilitating prenatal care and consequently may have a healthier lifestyle than unemployed women (Savitz et al., 1990). Hence, it would appear with the Teitelman and Ramirez designs that a more accurate comparison would be achieved due to the women, all employed, having more similar baseline characteristics (Keith & Luke, 1993).

Composite Scores for Describing Work

Job title categorizations are limited by possible misclassification, variation in what the individual woman experiences while doing the job and actual duration on the job. This misclassification and variation could be corrected by quantification in the form of measures of multiple work stressors (Marbury, 1992).
Table 2.3 Occupational Fatigue Index as Defined by Five Sources of Fatigue: Each Score

is "High" If One or More Elements of the Job Listed is Present

Occupational Fatigue Source	"High" Score If
Posture	Posture in standing position more than Three Hours per day
Work on Industrial Machines	Work on industrial conveyor belt; Independent work on industrial machine with strenuous effort or vibrations
Physical Exertion	Continuous or periodical physical effort Carry load of more than 20 pounds
Mental Stress	Routine work; varied tasks requiring little attention without stimulation
Environment	At least two of these three elements: significant noise level; cold temperature, very wet atmosphere; manipulation of chemical substances

Mamelle and associates (1984) constructed the first composite score describing the effect of work on the incidence of preterm delivery from the responses of 1928 employed women who had just delivered; 112 (5.8%) of these working mothers had premature births. These cases were matched with 3 controls (resulting in 336 controls) having the same age ± 2 years, ethnic origin, socioeconomic class, parity, previous prenatal problems in pathology during pregnancy. A fatigue index which breaks down a job into five sources -- posture, work on industrial machine, physical exertion, mental stress and environment (See Table 2.3)-- was constructed which is still a prototype in the field. Mamelle found a significant relationship (t=4.56, p<.05) between prematurity rate and the number of high scores on the job (when 3 sources of fatigue are simultaneously rated as high) in a multiple logistic analysis controlling for low socio-economic level, unmarried mother, low maternal education, low maternal age (<20 years), parity, previous prematurity and obstetric pathology. A limitation of this study is that measures of smoking and maternal nutrition were not included in the logistic regression model as they were considered related to low birthweight rather than preterm birth.

Other composite score tools have been constructed by subsequent researchers in relation to the populations they were studying. Armstrong and associates (1988) studied 22404 singleton pregnancies where the women were employed 30 hours or more a week and remained in the same conditions until at least the twenty-eighth week GA. The following occupational factors were measured: working hours, assembly line work, type of shift, work posture, weight lifting, noise, vibration, temperature, use of photocopier and visual display terminal. There was an increase in preterm birth with heavy lifting, long hours of work and shift work before the third trimester. Composite scores have also been studied with hospital workers (Saurel-Cubizolles et al, 1985), Finnish manual workers (Nurminen et al, 1989), Guatemalan office and manual workers (Launer et al., 1990) with success in predicting preterm birth (Barnes et al., 1991).

Methodological Issues

In regard to the above literature review on employment as a proxy for fatigue in relation to preterm birth, several methodological issues need to be discussed. They include: 1) accuracy of fatigue definition from the standpoint of employment, 2) definition of outcome, 3) study design, and 4) confounding factors.

Fatigue Definition.

One of the weaknesses of risk scoring tools for preterm labor and birth was the lack of clear definition of individual risk. In the research on employment as a proxy for fatigue, definitions of the fatiguing components of employment that made work deleterious in pregnancy have been vague. Early studies (Douglas, 1950; Illsey et al., 1954; Stewart, 1955) defined employment in terms of duration. It was presumed that employment itself was injurious and the longer one worked, the more negative the outcome was for the mother. Not surprisingly, results of those early studies were mixed depending on the population studied and research design. Although this is historical material, it is relevant to present day assessment tools where "work outside home" is simply mentioned without further elaboration.

Job titles have been used as an alternate means for defining employment. This practice has been common especially in analysis of birth certificate data. Large numbers of women have been sampled but internal validity has been lost due to lack of preciseness of definition of work and its implied fatigue. Use of job title also results in inevitable misclassification (Simpson, 1993; Marbury, 1992). Such measurement error can reduce an apparent association between the type of job and outcome.

A third assessment technique has been to ascertain certain components of jobs. Questions have been asked about the amount of lifting, standing, commute time and so on. The validity of these questionnaires is dependent on the study subject's ability to accurately recall and quantify the strenuous aspects of her job. If the questionnaire is administered after delivery, as with many of the case control and retrospective crosssectional designs, the study is at risk for recall bias. However, despite threats to validity, questionnaires in the form of composite scoring consistently show a strong association between strenuous physical activity at work and preterm delivery (Keith & Luke, 1993).

Fatigue originating from places other than the workplace is often ignored in research on pregnancy and work (Chamberlain, 1983; Stein et al., 1986; Simpson, 1993). The amount and type of physical exercise, housework and/or help in performing it and the ages and number of children at home may affect the overall fatigue severity of the pregnant woman. In one study (Berkowitz et al, 1983), where leisure-time physical exercise as well as activity on the job were considered, those who participated in sports or physical fitness exercises in the first and second trimester had no decreased risk of preterm delivery (OR=0.53, 95% CI 0.36, 0.78, p<.01). Most quit working during the latter part of the third trimester with the average lag between employment termination and delivery between 7.9 (cases) and 9.1 (controls). There was no difference in the number of hours of housework and child care in cases and controls. On the other hand, three studies in less developed countries (Tafari et al., 1980; Launer et al., 1990; Barnes et al, 1991) actually did measure the influence of household work on pregnancy outcomes, including housework that produces income for the family. Birthweight was significantly lowered but, as a continuous variable, a drop in birthweight did not require as much statistical power.

Finally, relatively expensive methods to assess fatigue may involve more objective observation, including the direct measurement of metabolic activity in kilocalories per kilogram per unit time. Barnes and associates (1991) did measure energy expenditures (kcal/kg/min) from home and work activities on 2741 pregnant Filipino women. Total energy expenditure increased birthweight significantly whether the women worked outside the home, were engaged in home economic (adding income) activity or in no economic activity (eg. housewife). This may have been an indication of physical fitness rather than physical stress. The other difficulty with measuring activity in this study was using 0.06 kcal/kg/min whether this activity was in the workplace or at home. The investigators admitted that the measures for the women working outside the home were not as exact.

In similar study in Australia, Magann and associates (1996) studied 2743 pregnant women whose energy expenditures were calculated based on employment, domestic work at home, leisure and athletic activities. The women were divided into five groups based on their daily kilocalorie expenditure. Multivariate analyses revealed that apparent effects of exercise were due almost entirely to confounding variables—maternal height, weight, age, socio-economic score, smoking, parity and race---and not to the level of activity itself (eg. the lower socio-economic, aboriginal group had less energy expenditure). The medium energy (2701-2900 kcal) expenditure group had the highest infant birthweights (p=.007) but the difference between 3200 and 3300 grams was not clinically important. There were no differences in the frequencies of preterm labor and birth. Hence, the Barnes and Magann studies show that the kilocalorie method of measuring energy expenditure still needs refinement. This refinement could include (1) a better method of defining the energy expenditure of various activities in different settings or (2) choosing a design where sampling will not result in redundancy of energy expenditure with demographic characteristics.

Findings on the relationships between preterm labor and hemoglobin or hematocrit (as proxies for fatigue) have been mixed. While Lieberman and associates (1980) found preterm labor to increase with decreased hematocrit (more related to maternal nutritional intake), more recent researchers have not supported this relationship (Lu et al., 1991; Fukushima & Watanabe, 1991; Blankson et al., 1993). Naeye and Tafari (1983) attributed the high hemoglobin levels and negative outcomes to low placental blood flow (more related to maternal activity and position), fetal hypoxia and increased hematopoiesis.

Outcome definition

Although this review has focused on preterm delivery as the outcome, many of the studies on pregnancy outcome have actually examined birthweight (<2500 grams) or both GA and birthweight. It is important to determine whether the low birthweight (LBW) was due to preterm birth or intrauterine growth retardation (IUGR) or a combination of the two This is a significant distinction, as LBW due to IUGR indicates a different pathophysiologic mechanism. With IUGR, it is the fetus who is unable to achieve its growth potential due to intrinsic and extrinsic factors. Intrinsic factors have to do with genetic abnormalities or infectious agents altering the normal process of cell division. Extrinsic factors include largely fetal malnutrition and maternal stress or chronic hypertension resulting in placental insufficiency (Blackburn & Loper, 1992). Hence, pathologically, low birthweight due to IUGR is both a problem of fetal and maternal stress prematurely leading to uterine irritability and cervical change and delivery of a small infant. Studies that do not make this distinction are difficult to interpret. Also it is important to report whether the preterm delivery was elective. Obstetric conditions such as severe preeclampsia and chronic medical complications, may be indications for induction of labor before 37 weeks.

Other sources of confusion include the basis of GA and whether to treat GA as a dichotomous or continuous variable. Except for the early British studies that did not have the benefits of more sophisticated ultrasonic pregnancy dating, most researchers used more than one method to estimate GA. These included subject's recall of last menstrual period, physician's estimate from fundal growth and Dubowitz pediatric examination. The Dubowitz test may not be valid for assessing African American babies, since they tend to display more mature features on examination (Zuckerman et al., 1986).GA, similar to birthweight, is more clinically significant as a dichotomous variable as infants born before the cut-off date (37 complete weeks since the first day of the last menstrual period) have significantly more morbidity and mortality. However, as a dichotomous variable, GA (for preterm birth defined as before or after 37 weeks) has much less statistical power to detect subtle effects. Although an important study in the pregnancy and employment literature, the Naeye and Peters (1982) large national sample findings would have had more impact for the clinician had GA been affected. Instead, there was a decrease in birthweight, all within the 3000 gram range, producing infants with minimal morbidity and mortality.

Study design.

Retrospective cross-sectional, case control and prospective cohort have been the three study designs used to assess the relationship between employment and fatigue with pregnancy outcome. In the retrospective cross sectional design, women are interviewed after delivery about all the stressors they experienced during pregnancy while the case control design divides a sample between those who already experienced the outcome and those who did not. These designs have been widely used due to their relative ease in implementation and access to incidents occurring later in pregnancy. However, these designs are not without limitations. Data gathered retrospectively are subject to misclassification or recall bias, especially if the pregnancy outcome is negative. A reasonable time for interview after delivery can be scheduled according to the convenience of the investigators but, in some cases, has increased bias. For instance, in Douglas (1950) study, women were interviewed 8 weeks after delivery. In Saurel-Cubizolles' study, women were questioned when they got back from maternity leave (Saurel-Cubizolles et al., 1984). It is not surprising that Peoples-Sheps and associates (1991) and Hartikainen-Sorri and Martti-Sorri (1989) were concerned with recall bias when their study designs allowed up to a year for interviewing after delivery. Another limitation in this design is the temporal sequence between outcome and stressor. If the stressor is duration of employment, a woman who is working in a strenuous job may be advised to leave work early which Savitz (1990) calls the "insecure worker effect." If this occurs enough times in the sample, it may appear that working longer may have more favorable outcomes than leaving work earlier. This may account for the discrepant results of the work duration studies in Britain (Douglas, 1950; Illsey et al., 1954; Stewart, 1955; Drillien, 1957).

In prospective studies, women are enrolled usually when they register for prenatal care and are then followed through pregnancy. Information on fatigue in employment can be collected and updated in the design. Misclassification still can occur with vague definitions of fatigue or components of work as discussed above but it will not be compounded by recall bias of a retrospective design. Also, the temporal sequence problem of stressor and outcome is overcome. However, preterm birth is a relatively rare occurrence in the general population. Even in high risk populations, such as the inner city African American women in Main and associates' (1987) study, preterm birth rate was only 14.6%. Hence, a prospective design would either require a large population exposed to fatiguing work, as found in the Ethiopian population carrying water jars and grinding grain (Tafari et al., 1980) or require screening large numbers of women at their first prenatal visit and categorizing them by standing, active and sedentary activities (Teitelman et al., 1990).

Confounding Variables.

Many factors have been known to affect the duration of gestation which necessitates the importance of statistical multivariate analysis. Many of the earlier studies used univariate analysis including Chi square and t-tests to analyze relationships between variables. This limited the ability of the investigators to adequately analyze the relationship between fatigue related factors and preterm birth. Logistic regression has been the most useful multivariate statistic to assess, predict and determine risks for preterm birth or labor as the dependent variable.

Socio-economic Group as a Key Confounder Previous preterm birth or pregnancy loss, cigarette smoking, low pregnant weight and diethylstilbestrol exposure have had a clear and documented association with preterm birth (Shiono & Klebanoff, 1993). However, socio-economic status is the most serious confounding factor affecting the relationship between work stressors and pregnancy outcome. Even when analyses control for epidemiological markers of socio-economic status (such as maternal age, parity, marital status, poverty, ethnicity, or restricted access to prenatal care) the effect of low socioeconomic status is still evident. This may be because the typical factors which account for socioeconomic status, mother's educational level and family income, may not adequately capture the concept. It may be that more factors such as the pregnant woman's father's occupation, as analyzed by Drillien (1957), may add to the accuracy of the assessment of this factor. Whatever the definition of socioeconomic status, there is definitely a strong correlation between socioeconomic group and lower paying jobs which are physically demanding.

The problem of socioeconomic confounding can be best handled by including only subjects of the same socioeconomic class in the study or stratifying by socioeconomic class in the analysis. With the latter approach, modification of social class could be evaluated for its effect. Previous studies which have stratified in this manner (McDonald et al., 1988; Saurel-Cubizolles et al., 1987), however, have not had enough women with physically demanding jobs in the upper socio-economic stratum to analyze the relationship between employment fatigue and pregnancy outcome.

Recognizing the difficulty of separating the effects of work from those of socioeconomic status, Klebanoff and associates (1990) studied the pregnancy outcomes of 4412 women who graduated from medical school and compared them to the outcomes of 4236 wives of their male classmates. Although the women residents worked many more hours than the wives of male residents, preterm delivery rate was not different (6.5% versus 6.0%) although preterm labor (11% versus 6.0%) was higher. A possible explanation is that the women residents had more access to early diagnosis and treatment of preterm labor and, hence, the results cannot be generalized to other populations. Other studies of physicians showed significant results regarding low birthweight during residency (Grunebaum et al., 1987) and preterm delivery in practicing physicians (Miller

et al., 1989) but the latter only involved 67 pregnancies and not necessarily during a time of high fatigue.

Another population of pregnant women with more homogeneous characteristics to decrease socio-economic confounding would be active duty military women. Like the physician residents, the active duty military woman does physically demanding work. Her work may require heavy lifting, working in confined spaces, twisting, bending and stooping. At the onset of pregnancy, the active duty member may be given exemptions from a number of activities but still is expected to perform all duties not detrimental to her pregnancy until the onset of labor.

The military samples studied to date have contained many of the confounding risk factors related to preterm delivery including largely African American, single and primiparous women giving birth to premature infants (Green, 1990). On the other hand, this population is homogeneous in regard to access to prenatal care, meeting health requirements at entry to service, passing annual physical fitness examinations and yet containing more non-white women than is representative of the U.S. population (Institute of Medicine, 1995). Due to random drug screening, recreational drug use is minimal. Hence, the military women provide an opportunity to design a study on the effects of physical demands on pregnancy outcomes with many of confounding variables accounted for, especially some key socio-economically related variables.

Military Studies

Unfortunately, a literature review revealed that a number of the studies on military populations have methodological difficulties. Fox and associates (1977) did a retrospective cross-sectional study comparing 196 Air Force active duty, 196 non active

women matched for age and parity and 300 general obstetric clinic deliveries. Active duty members had a two fold increase in preeclampsia and a five fold increase in premature labor and anemia. Statistical analysis was by Chi square, which was adequate to compare certain demographic variables and complications between the three groups, but not adequate to account for confounding variables. Adams and associates (1993) in a review of Fox's study felt that the 2% low birthweight statistic was "unbelievably" low. No attempt at analyzing components of work in the active duty women was done. However, research via job title was the type of investigation done in the work and pregnancy outcome literature at the time of the study (1974-1976). Kruger (1978) also retrospectively studied 146 Air Force women and 146 civilian controls matched by age levels of active duty members but no activity levels were recorded for the civilian controls; hence, no comparison in this area could be done. Gestational age verification was done by pediatricians using the Dubowitz scoring which also limited the internal validity. Like the Fox study, bivariate statistics were used, which decreased the ability to distinguish among confounders.

Military Studies and Job Stress.

Job stress based on military occupational specialties (MOS) were defined in a case control study of 6674 active duty Army women between 1981-1984 (Ramirez et al., 1990). Risk factors for preterm birth included age, race, pay grade, length of military service, marital status, education, occupational aptitude score, job skill level and type of military unit. Military women of different activity levels (based on varying requirements of upper body strength) were compared with each other instead of civilians. As mentioned above in the analysis of the healthy worker effect, this further strengthened the study establishing common baseline characteristics of the study participants. In a multifactorial model using logistic regression, the three significant predictors of preterm birth were physical activity, race and military pay grade. Pay grade is a socioeconomic effect modifier, as is race. However, more seriously, information was not available regarding nutritional practices, smoking habits, alcohol consumption or pregnancy complications. Hence, while there was a better definition for physical stress (job categories requiring different levels of upper body strength), this study was limited by the omission of key confounding factors.

The fourth study, done at the Naval Hospital at Camp Lejeune from 1988-1991 (Magann & Nolan 1991), returned to the less satisfactory format of job title without further delineation of physical activity in evaluating the impact of psychosocial stress and physical activity on pregnancy outcome. Furthermore, dependent wives were used as controls without any assessment of their activity level but were matched by age and gravidity to the active duty group. Cesarean births, maternal transfer, preeclampsia and IUGR were significantly increased in the active duty group, using Chi square analysis. Hence, again, confounding variables were not considered. The investigators quoted the physical activity policy of the military but did not actually measure the activity level of the study participants.

A well-designed study was done at four Army tertiary care facilities to examine differences between African American and Caucasian service members in their preterm delivery rates (Adams et al., 1993). Although the study did not focus on job stress, relevant risk factors in a military environment for preterm delivery were examined for each group and analyzed through logistic regression. An interesting finding was that while White enlisted women had rates of preterm delivery 25-45 % higher (depending on the Medical Center) than would be expected of a comparable American woman (based on 1987 National Natality Statistics), African American enlisted woman had a preterm birth rate that was 10% lower than expected. A possible explanation, of special interest when one considers the issue of socioeconomic confounding, is that the African American enlisted woman may be more advantaged than the normative African American woman while the White woman is less advantaged in a military environment. One reason may be that the active duty African American woman may find the military health care environment where she is given priority treatment (see Appendix I), a bigger contrast to what she would find in a civilian setting than the White woman in the same environment.

Hence, although research with the active duty military population has had some serious flaws, its relatively homogeneous characteristics (fewer socioeconomic related confounding factors) make it an ideal population for studying the effects of physical fatigue on pregnancy outcome.

Psychological Stress

Besides definitions, design, and confounders such as socioeconomic status and job stress, another major methodological issue in the work and pregnancy outcome research is the effect of psychological stress. It is a major variable in the physician resident and active duty military studies mentioned above largely due to the fact that it has the same physiological effect on pregnancy as fatigue (Main, 1988). Mamelle and associates (1984) considered "mental stress," a component of their occupational fatigue scale, as work that was routine or required little or nor mental stimulation. Subsequently, Mamelle's group developed a tool for the evaluation of psychological attitudes toward pregnancy as they may relate to preterm birth incidence (Mamelle et al., 1989). The content was based on interviews with women who had given birth prematurely. This tool called the Pregnancy Psychologic Attitudes Test (PPAT) consists of 6 dimensions (See Table 2.5). It was prospectively tested on 1500 women at 20-24 weeks GA. After controlling for parity, obstetric history and marital status, a logistic regression model

Psychologic Dimension	Main Concepts
Pregnancy's Effects on the body	Bodily discomfort; poor mental image, embarrass- ment or shame in public; uncomfortable seeing oneself gaining weight
Feelings of fulfillment during pregnancy	Lack of contentment; anxiety; negative feelings about mothering; pregnancy felt as a restriction
Attitudes toward daily life and behavior while pregnant	A need to do everything quickly; a need to have everything planned in advance; a feeling that "the sooner the delivery, the better"
Role of the baby's father	Wanting a child for oneself; father's lack of involvement; husband indifferent
Family ties	Negative feelings of belonging; an unwanted baby feeling different from the others
Beliefs and Superstitions	Sense of a family destiny; a belief that cravings pregnancy should be satisfied; beliefs in the power of society, religion and science to make life easier; Superstitions

Table 2.4 Content of Pregnancy Psychologic Attitudes Test (PPAT)

confirmed the relationship between the PPAT score and risk of preterm birth (OR=1.46, 95% CI=1.16, 1.82) differentiating between 1375 term births and 125 preterm births.

In contrast, a broader source of stress was considered by Newton and Hunt (1984),

in their study of 250 women who were interviewed about adverse life events three times

during pregnancy and shortly after delivery. Major life events were associated with

preterm birth (p<.001). The problem with this study was that sample size was small with only 20 mothers giving birth to infants who were either preterm or low birthweight and only univariate results were reported. In addition, although this study was prospective, the life changes that occurred in the latter part of the pregnancy, where most of the significant associations were noted, were recorded retrospectively, increasing the possibility of biased results.

Homer and colleagues (1990) in a study of 786 employed pregnant young women included in the National Longitudinal Survey of Labor Market Experience, presented still another definition of psychologic stress. After controlling for physical exertion and psychologic stress entailed in job titles, it was determined that women who were working in jobs characterized by high levels of psychologic demand with little control over the pace of the job, were at higher risk of preterm birth (RR= 8.1; 95% CI 1.5-50.2) if they were not motivated to continue working.

Finally, just as physical exertion is beginning to be defined from the standpoint of more than just the workplace, psychologic exertion has been extended to the household role for pregnant women. Pritchard and Mfphm (1994) studied 939 women with one previous successful delivery at 20 and 30 weeks gestation for perceived difficulties with the household role and an association with preterm birth. Feelings at 20 weeks gestation regarding role strain (OR= 2.86, 95% CI= 1.05-7.76) and preterm birth based on a self-report questionnaire validated the importance of household role strain as a predictor.

Summary

In summary, fatigue is an intricate phenomenon affected by a number of factors in pregnancy. Fatigue is best conceptualized for working pregnant women as related to internal and external environmental demands experienced on a continuum depending on energy expenditure. Fatigue as a symptom is assessed and the woman responds to it with changes in physical and psychological signs and symptoms.

This literature review, additionally, has shown that fatigue, under the assumption that it has been used as a proxy variable for occupational conditions, has been associated with preterm labor and birth when certain methodological problems have been overcome. These problems include fatigue as part of a survey checklist, definition of working conditions, definition of outcome, study design including sample size and timing of data collection and control for confounding factors, especially non-modifiable historical risk factors, socio-economic group, and physical and psychological stress. A well-designed study with a more homogeneous sample of women with controls for socio-economic and physical and psychological stress factors, is needed to clarify the complex interrelationships of fatigue in pregnancy and the associations between fatigue severity or occupational stressors and preterm labor or delivery.

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CHAPTER 3

METHODOLOGY

Introduction

This chapter focuses on the methodology used in this research on fatigue and preterm labor and birth in active duty military women. First the research aims are restated in terms of hypotheses for the study. Second, the assumptions and definition of terms are specified. Third, the research design is introduced followed by a description of the setting, sampling and data collection methods, including techniques and instruments. Finally, the statistical plan for data analyses based on the study hypotheses will be reviewed.

Hypotheses

The following hypotheses for each aim are included in this study:

Aim 1: Describe the internal environmental demands (depression, anxiety, sleep disturbance, age, diet patterns, weight gain, smoking, alcohol, caffeine intake, exercise) and external environmental demands (marital status, social support, housing, occupational conditions, rank, education, income, life events, ethnicity) as correlates of fatigue in pregnant active duty women.

Hypothesis 1: There will be statistically significant relationships between internal

and external environmental demands and the perception of fatigue severity.

Aim 2: Determine the relationship between perceived fatigue severity and occupational fatigue at 22-26 weeks gestation and the incidence of preterm labor and birth in active duty women.

Hypothesis 2.1: There will be a statistically significant difference in the mean perception of fatigue severity at 22-26 weeks GA between active duty women who have preterm labor and those who have do not have preterm labor.

Hypothesis 2.2: There will be a statistically significant difference in the mean perception of fatigue severity at 22-26 weeks GA between active duty women who have preterm birth and those who have do not have preterm birth.

Hypothesis 2.3: There will be a statistically significant difference in the mean perception of occupational fatigue at 22-26 weeks GA between active duty women who have preterm labor and those who have do not have preterm labor. Hypothesis 2.4: There will be a statistically significant difference in the mean perception of occupational fatigue at 22-26 weeks GA between active duty women who have preterm birth and those who do not have preterm birth.

Aim 3: Determine the relationship between perceived fatigue severity and occupational fatigue over time and the incidence of preterm labor and birth in active duty military women.

Hypothesis 3.1: The change in mean perception of fatigue severity over two consecutive work days at 22-26 weeks GA will significantly predict the incidence of preterm labor in active duty military women.

Hypothesis 3.2: The change in the mean perception of fatigue severity over two consecutive work days at 22-26 weeks GA will significantly predict the incidence of preterm birth in active duty military women.

Hypothesis 3.3: The change in weekly work hours from 22-26 weeks gestation to delivery will significantly predict preterm labor in active duty military women.

Hypothesis 3.4: The change in weekly work hours from 22-26 weeks gestation to delivery will significantly predict preterm birth in active duty military women.

Assumptions

There are several assumptions in this study. The first assumption was that active duty military women experienced and described the symptom of fatigue as a result of being pregnant. Internal environmental factors (age, diet patterns, weight gain, smoking, alcohol, sleep disturbance, depression and anxiety) and external environmental demands (marital status, social support, housing, occupational conditions, rank, life events and ethnicity) are assumed to influence their perception of fatigue. Previous studies of occupational factors influencing gestational duration actually were measuring employed pregnant women's fatigue levels. Fatigue levels vary at different times of the day and work hours change during pregnancy. Pregnant active duty military women are assumed to be physically fit, have good access to prenatal care and do not engage in illegal drug use.

Definition of Multi-Instrument Variables and Key Terms The following definitions are used for variables that are measured by more than one instrument.

<u>Fatigue</u>. Fatigue is the generalized, subjective perception of energy on a continuum which may fluctuate by time of day. It is operationalized as a response to the stressors of pregnancy and measured by Visual Analog Scale (VAS), fatigue and vitality scales of the Profile of Moods States (POMS) and the Pearson-Byars Scale in the 2-day diary. High fatigue is characterized by the perception of low energy and low fatigue by higher energy.

<u>Gestational Age (GA)</u>. Gestational Age is defined in this study as the age of fetus based on ultrasound done at 16-18 weeks. If that assessment was not available, GA was

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Table 4.3

Mean Scores on Study Variables: All Subjects, Internal Demands (n=359)						
Mean	SD	Sample Range	Instrument Range	10		
				Ş		
4.16	4.03	0 - 18	0 - 20			
5.13	3.67	0 - 18	0 - 20	10		
				Ne		
48.9	15.78	8 - 91	0 - 140	12		
2.83	2.09	0 - 7	0 - 7			
5.13	2.13	0 - 7	0 - 7	14		
3.56	2.44	0 - 7	0 - 7			
4.16	1.84	0 - 7	0 - 7			
3.41	2.26	0 - 7	0 - 7			
4.38	2.13	0 - 7	0 - 7	75		
2.93	2.22	0 - 7	0 - 7	· .		
3.32	2.25	0 - 7	0 - 7			
4.03	2.05	0 - 7	0 - 7			
4.34	1.90	0 - 7	0 - 7	5		
4.45	1.68	0 - 7	0 - 7			
0.89	1.39	0 - 7	0 - 7			
4.06	2.19	0 - 7	0 - 7			
0.96	1.86	0 - 7	0 - 7	ť		
0.35	1.18	0 - 7	0 - 7			
0.00	0.36	0 - 6	0 - 7			
0.04	0.41	0 - 5	0 - 7			
none			0 - 7	Â(j		
0.00	0.10	0 - 2	0 - 7			
0.00	0.17	0 - 3	0 - 7	χċ		
0.00	0.47	0 - 5	0 - 7			
	Il Subjects, Mean 4.16 5.13 48.9 2.83 5.13 3.56 4.16 3.41 4.38 2.93 3.32 4.03 4.34 4.45 0.89 4.06 0.96 0.35 0.00 0.04 none 0.00 0.00	Il Subjects, Internal De Mean SD 4.16 4.03 5.13 3.67 48.9 15.78 2.83 2.09 5.13 2.13 3.56 2.44 4.16 1.84 3.41 2.26 4.38 2.13 2.93 2.22 3.32 2.25 4.03 2.05 4.34 1.90 4.45 1.68 0.89 1.39 4.06 2.19 0.96 1.86 0.35 1.18 0.00 0.36 0.04 0.41 none 0.00 0.00 0.17 0.00 0.47	Il Subjects, Internal Demands (n=3)MeanSDSample Range4.164.03 $0 - 18$ 5.133.67 $0 - 18$ 5.133.67 $0 - 18$ 48.915.78 $8 - 91$ 2.832.09 $0 - 7$ 5.132.13 $0 - 7$ 5.132.13 $0 - 7$ 3.562.44 $0 - 7$ 4.161.84 $0 - 7$ 4.161.84 $0 - 7$ 3.412.26 $0 - 7$ 4.382.13 $0 - 7$ 4.391.39 $0 - 7$ 4.032.05 $0 - 7$ 4.341.90 $0 - 7$ 4.451.68 $0 - 7$ 0.891.39 $0 - 7$ 4.062.19 $0 - 7$ 0.961.86 $0 - 7$ 0.000.36 $0 - 6$ 0.04 0.41 $0 - 5$ none 0.00 0.17 $0 - 3$ 0.000.17 $0 - 3$	Il Subjects, Internal Demands (n=359)MeanSDSample RangeInstrument Range4.164.03 $0 - 18$ $0 - 20$ 5.133.67 $0 - 18$ $0 - 20$ 5.133.67 $0 - 18$ $0 - 20$ 48.915.78 $8 - 91$ $0 - 140$ 2.832.09 $0 - 7$ $0 - 7$ 5.132.13 $0 - 7$ $0 - 7$ 3.562.44 $0 - 7$ $0 - 7$ 4.161.84 $0 - 7$ $0 - 7$ 3.412.26 $0 - 7$ $0 - 7$ 3.322.25 $0 - 7$ $0 - 7$ 4.032.05 $0 - 7$ $0 - 7$ 4.341.90 $0 - 7$ $0 - 7$ 4.341.90 $0 - 7$ $0 - 7$ 0.891.39 $0 - 7$ $0 - 7$ 0.961.86 $0 - 7$ $0 - 7$ 0.961.86 $0 - 7$ $0 - 7$ 0.000.10 $0 - 2$ $0 - 7$ 0.000.10 $0 - 2$ $0 - 7$ 0.000.10 $0 - 2$ $0 - 7$		

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XW

calculated from the last menstrual period (LMP). If LMP was not available, Dubowitz newborn assessment of GA was used.

<u>Preterm Labor.</u> Preterm Labor is defined as cervical change as a result of uterine contractions occurring after 20 weeks gestation and <37 weeks gestation.

<u>Preterm Birth</u>. Preterm Birth is defined as the non-induced delivery of an infant at <37 weeks GA or <259 days gestation.

<u>Active Duty Military</u>. Active Duty Military include women who are serving on a full time basis (as opposed to selected reserve, inactive or retired) in U.S. Army, Air Force, Navy, Coast Guard, Marines or Public Health Service. Under this job category two classifications: officer and enlisted which is further described in Appendix E.

<u>Nutritional Status.</u> Nutritional status is operationalized as absence of anemia (28 week hemoglobin ≤ 10 gm/dl) and use of prenatal vitamins and iron.

<u>Total weight gain</u>. Total weight gain is defined as the difference between prepregnant weight (recalled) and weight at last clinic visit before delivery.

Rate of weight gain. Rate of weight gain is defined as the total weight gain divided by the gestational age of the infant at delivery.

Body Mass Index (BMI). BMI is calculated as the weight in kilograms divided by height in meters squared (kg/m²).

<u>Housing Conditions</u>. Housing conditions are operationalized by (1) nonoccupational living conditions ranging from barracks to detached home, (2) number of people and children less than 5 years old living in the house, (3) number of non-occupational roles: homemaking, parenting, volunteering, leisure activities, adult relationships, and student activities. Occupation. Occupation is defined as the job now held in the military categorized as one of 4 military occupational specialties: (1) mild/moderate stress (sedentary clerical positions, (2) intensive mental stress (air traffic controller, field radio operator), (3) exposure to hazardous materials (heavy equipment operator, small arms repair, firefighting specialist, and (4) physical stress (corpsman, nurse, military police, food service specialist).

Occupational Fatigue. Occupational fatigue is categorized by source of stress on the job in the last week, estimated using the Occupational Fatigue Index (see Table 2.4) to note the presence or absence of standing, work on industrial machines, physical exertion, mental stress and environmental conditions. This variable is also measured by hours of work per week, working nights or weekends, duty hours and commute hours.

Research Design

This research utilized a longitudinal descriptive prospective cohort design to describe the factors that contribute to fatigue severity in pregnant active duty military women and to determine whether the level of fatigue severity and occupational fatigue in the second trimester of pregnancy was associated with preterm labor or delivery.

At time I, active duty military women at 22-26 weeks GA were asked to provide quantitative and qualitative information regarding internal and external demands related to fatigue severity using instruments described in the data collection section below. The late second trimester (22-26 weeks) was selected as studies have shown the second trimester to be a time of increased energy and that a continued low energy level could be a marker for pregnancy complications (Cherry, 1989, Pitzer, 1989; Pugh and Milligan, 1993).

Data were collected at time I during a clinic visit where a paper and pencil instrument packet was completed. A diary was used to assess fatigue severity over 2

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consecutive work days (6 measurement times). After completion, it was mailed to the investigator in a pre-stamped envelope. A monthly phone call (5 measurement times) made to each woman to ask about the changes in weekly work hours and job type and the duration (in weeks gestation) she worked during the pregnancy.

At time II, about 5 months after the initial data collection was completed, the investigator arranged with Medical Records to pull the inpatient records of the subjects who delivered. Gestational age of the delivered infant, total pregnancy weight gain, hemoglobin at 28 weeks, physician's documented etiology for preterm birth and obstetrical and medical complications that occurred during the antepartum, intrapartum and immediate postpartum parts of the pregnancy were collected from the chart.

Setting

The study was conducted at Obstetrical-Gynecological (OB-GYN) clinics at four military medical centers throughout the United States. Each site had residency programs for training of staff physicians with similar treatment protocols. The sites were Tripler Army Medical Center (Honolulu, Hawaii), Naval Medical Center, San Diego (San Diego, California), Naval Medical Center, Portsmouth (Norfolk, Virginia) and David Grant Medical Center (Travis Air Force Base, California). Three of the sites were selected by consulting the Retrospective Case Mix Analysis System (RCMAS) for preterm births (ICD-644.21) among active duty members. In fiscal year 1994, these sites accounted for nearly 20% (n=94) of the preterm births among active duty members in the United States. Tripler and San Diego report about 700 births a year from active duty women. Portsmouth registers about 1300 births from active duty members. David Grant, with 180 active duty deliveries a year, was added due to proximity to the investigator's residence and to add more Air Force members to the study.

At Tripler, the main OB-GYN and Family Practice clinics were used with a small waiting room used for the questionnaire packets. Available clinic offices were used at 32th St, Coronado and Balboa clinics in San Diego, Sewell's Point Clinic and Boone Clinic at Portsmouth and the main OB-GYN and Family practice clinics at David Grant.

The study was conducted over a 15-month period from September 1995 to December 1996.

Sample

Human Subject Assurance

This study was approved by the University of California, San Francisco Committee on Human Research (H5464-11539-02) and by the review boards for the protection of human subjects of Tripler Army Medical Center (TAMC 29II95), Naval Medical Center, San Diego (CIP #S-95-LHOOOOO-091), Naval Medical Center, Portsmouth (#P95-L-HOOOOO-042:A) and David Grant Medical Center (#95-E0128). Informed consent was obtained from each subject in accordance with the guidelines of the Committee on Human Research at UCSF (see Appendix A for all consent forms).

Nature of Sample

Women from a consecutive sample of pregnant active duty personnel were invited to participate from 9 OB-GYN/Family Practice clinics connected with the 4 military medical centers.

Subjects were selected based on the following inclusion criteria:

1) no history of prior preterm birth or spontaneous abortion

2) over 18 years of age

- 3) 22-26 weeks gestation at enrollment
- 4) singleton pregnancy only
- 5) no history of chronic illness or obstetrical complication
- 6) no current treatment for vaginal or urinary tract infection
- 7) not currently diagnosed as being in preterm labor
- 8) intention of staying in military until delivery

Limiting the sample to active duty women who intended to stay in their respective services until delivery was based on the findings of Savitz and associates (1990) regarding employed women. They found that women who worked during pregnancy had especially favorable demographic and behavioral traits for positive pregnancy outcomes (i.e. no chronic illnesses, education, income, initiation of prenatal care, weight gain and smoking). Most active duty women are recruited into the service after they are 18 years of age which would exclude comfounding factors related to teen pregnancy. Excluding women with multiple gestation, current treatment for urinary tract or vaginal infection or current treatment for preterm labor (cervical changes) also controlled for known factors associated with preterm birth (Creasy, 1991).

Size of Sample

The sample size was estimated based on occupational activity scores serving as proxy variables for fatigue in prospective cohort studies examining the effect of work on the incidence of preterm birth (Teitelman et al., 1991; Launer et al., 1990). A computation of sample size to obtain significant power for statistical analysis was conducted as described in Cohen (1988). A proxy measure of fatigue, prolonged standing, was compared with active)

jobs. Standing was associated with 7.7% preterm birth rate compared to a 2.4% preterm birth rate with active jobs (OR=2.84). The effect size was about 0.30. Criteria for statistical significance were set at a power of 0.90 to increase the sensitivity of fatigue as a potential predictor and α of 0.05 (2-tailed). With an effect size of 0.30, 28 preterm birth patients would be needed in the sample (Cohen, 1988, p. 168). Assuming a conservative national preterm birth rate (8%) and an estimated 10% attrition due to relocation or other factors, the total sample needed with complete data was 380.

Based on estimates of active duty deliveries, it was calculated that 100 subjects each could be enrolled from Tripler and San Diego, 150 participants from Portsmouth and 30-50 subjects from David Grant within a 4 month enrollment period. It actually took 6 months to enroll the number of subjects required for the project.

Data Collection Methods

Technique and Procedure

Data collection was conducted by the Principal Investigator (PI) at David Grant and by trained Research Assistants (RA's) at the other sites. The RA's were given a 2-3 day training session (See Appendix B for training contents) where they were instructed on how to approach and attain consent from potential participants All active duty military personnel have a "20" prefix to their social security numbers). The RA's were trained to screen participants for inclusion criteria from their prenatal records and administer the questionnaire packets before or after a prenatal visit. The training session included: (1) written guidelines, (2) a sample questionnaire packet which the RA's administered to each other, (3) a script for approaching potential participants and for administering the questionnaire packet and (4) role playing to assist RA's in the best approach for recruiting subjects for the study. The RA's were also checked for reliability in screening charts by the PI. They each were checked for accuracy for determining whether a subject met criteria for the study by correctly noting criteria in 6 charts at least 90% of the time. Accuracy for inclusion was later double checked by the PI during the chart review during time II.

To minimize missing data, RA's were encouraged to: (1) stay with each participant during the administration of the questionnaire packet, be available for any questions, and check each tool for completeness at the end of the administration session, (2) emphasize the accuracy of follow-up phone numbers and the immediate completion of fatigue diaries on two consecutive work days and (3) call participants who did not send in their fatigue diaries in a timely manner (within 1 month). If no diary was received, the RA's did self report of verbal fatigue levels via a phone call) with less than 10% of the participants.

The RA's were instructed to work a schedule such that one of them was available for potential participants during a clinic visit every day there was a clinic session. Clinic personnel assisted in recruiting subjects by setting aside prenatal charts identified as "active duty less than 26 weeks gestation" sometimes calling RA's to alert them to the fact that potential subjects were due for appointments. Clinic schedules were also available one to two weeks in advance. Consents were signed with the plan that during the "window" of 22-26 weeks gestation, the subject would be given a questionnaire packet and diary.

A roster of participants was kept to document the time and day the participant was given the packet. Packets from Virginia, San Diego and Hawaii were mailed to the PI at two-week intervals. The principal investigator kept in close touch with the RA's to determine whether diaries were being sent and if there were any questions that needed to be answered. Some questions included where to store questionnaire packets, how to deal with clinic personnel to assist with the project, how to ensure that potential participants would show up for an appointment and stay in contact with the RA.

Telephone follow-ups consisted of monthly phone calls made to the participant's work or home regarding numbers of hours she was working during the preceding month and the type of job in which she was working. The RA's recorded the number of hours and work type on a form (see Appendix B) which was included in the participant's original questionnaire packet. The RA's continued to call the participant until she delivered.

After the initial training session, the principal investigator made two additional visits to each site. One was a mid-term visit for the purpose of meeting with all of the RA's and solving problems with recruitment and retention of subjects (obtaining both work and home phone numbers, checking with clinic personnel about change of numbers). A newsletter (see Appendix C) with helpful suggestions on how to enroll subjects, was sent to RA's in Hawaii and Virginia after a visit to the San Diego site.

The final visit was for time II of the study. The principal investigator made arrangements with the Medical Records of each site two months in advance by sending in all names and social security numbers of participants. A point of contact was made and he/she directed employees in the department to pull charts of mother and baby delivered from the pregnancy that was monitored. RA's that were available for the chart review were also given dates when the review would occur.

Another set of written instructions (see Appendix D) was created for the chart review. This included instructions on how to enter data into SPSS 6.1 for Windows, what variables needed to be examined and how to save data collected directly from charts onto

Table 3.1 Data Collection Plan

Baseline	Approach, Obtain Consent							
	Screen for inclusion criteria							
	<u>Color/Number code for each Site</u> Tripler - light pink, 1000 series David Grant - light blue, 2000 series San Diego - light green - 3000 series							
	22-26 weeks gestation	Profile of Moods States (shortened version)						
-	Visual Analog Scale-Fatigue							
	Sleep Disturbance Scale							
	Life Events Questionnaire							
	Support Behavior Index (shortened version)							
	Occupational Fatigue Index							
	Health Habits Questionnaire							
	Demographic Questionnaire							
	Fatigue Diary (mailed to principal investigator)							
26-30 weeks gestation	Hours Worked, Occupation (Telephone follow-up)							
30-34 weeks gestation	Hours Worked, Occupation (Telephone follow-up)							
34-38 weeks gestation	Hours Worked, Occupation (Telephone follow-up)							
38-42 weeks gestation	Hours Worked, Occupation (Telephone follow-up)							
Postpartum Chart	Gestational Age of delivered infant,							
Review	Reason for preterm birth if relevant							
	Medical and Obstetrical Complications							
	Weight Gains							
	Pre-pregnancy Weight							
	28 week Hemoglobin and Hematocrit							

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Months	1	2	3	4	5	6	7	8	9	10	11	12
Hire and/or Train Research Assist.	@									@	@	@
Data Collection Site #1		*	*	*	*	#	#	#		+		
Site #2		*	*	*	*	#	#	#		+		
Site #3					*	*	*	*	#	#		+
Site #4			*	*	*	*	#	#	#		+	
Data Coding	xx											XX
Data Entry		XX	xx	xx	xx					XX	XX	XX
Quality Control Evaluation		xx		xx						xx		
Data Analysis			1	1	xx	xx						XX
Data Interpretation							xx					xx
Consultation (Statistical)	xx			xx				xx			xx	
Final report											XX	XX
Presentations												XX

 Table 3.2 Original Time Plan for the Study

 $@= 2-3 \text{ days} * = \text{Initial enrollment, instruments, survey packet} | = \text{Reliability,} validity of instruments} # = Telephone follow up, + = Chart review with direct data entry via laptop computers; took 3-5 days$

Site #1 - San Diego; Site #2 - Tripler; Site #3 - Portsmouth; Site #4 - David Grant

floppy disks and hard drives. Similar to the screening of charts for inclusion in the study, the RA's were also checked for reliability in attaining data from the charts by the principal investigator. Accuracy in attaining data from 6 charts was considered satisfactory if greater than 90%.

Instruments used and the sequencing of data collection are presented in the data collection plan (see Table 3.1), and time table for data collection (Table 3.2).

Instruments

The instruments used in this study will be discussed in the order that they were presented to the study participants. The packet of questionnaires took from 30-45 minutes to <u>administer</u>. The fatigue diary took 5 minutes to complete at each of the six time points (morning, noon and evening for two consecutive work days). The telephone follow-up took l less than ten minutes of the participants' time.

Time One Data Collection

Profile of Mood States (POMS)

The POMS was used to assess aspects of current, relatively transient mood states by self report (see Appendix B) Originally developed as a 65-item scale by McNair and associates (1971), the short form consists of 30 adjectives forming the six subscales of tension-anxiety, depression-dejection, anger-hostility, fatigue, confusion-bewilderment and vigor rating on a 0 (not at all) to 4 (extremely) scale.

Subjects are instructed to indicate the extent to which they have experienced these adjectives during the past week including that day. Scores for each mood factor are obtained by summing up the responses for the adjectives defining the factor and can range from 0 to 20. The total mood score was not used for this study. Only the fatigue (5

items), depression (5 items), tension (5 items) and vigor (5 items) subscales were used in the analysis.

For an outpatient sample, internal consistency reliabilities (Kuder-Richardson 20) in the six scales range from 0.75 in confusion-bewilderment scales to 0.90 in the vigor scale. Independent researchers have established content, predictive and construct validity of the POMS (McNair et al., 1992). The POMS has been used in a longitudinal study with pregnant women (described in Chapter 2) undergoing amniocentesis and chorionic villus sampling (Tunis et al., 1990).

Visual Analog Scale for Fatigue (VAS-F)

The VAS-F was used to assess the subjects' perceptions of fatigue severity. It consists of 18 items related to fatigue (13 items) and vigor (5 items). Each line has bipolar anchors with related descriptors. The subject needs to place a mark along each of the 18 lines to indicate how they feel. The mean fatigue score is computed by summing the 13 scales and dividing by 13 and the mean energy score by summing the 5 scales and dividing by 5. Scores range from low fatigue (0) to high fatigue (100) and low energy (0) to high energy (100). Cronbach's alpha has ranged from 0.94 to 0.96. Concurrent validity has been established with the Stanford Sleepiness Scale and the fatigue subscale of the POMS (r=0.58, p<.01) and the vigor subscale of POMS (r=0.80, p<.01). Higher fatigue scores were noted in the evenings compared to the morning in a healthy sample (Lee et al., 1991). It has been used with pregnant patients (Lee & DeJoseph, 1992; Waters & Lee, 1996) and healthy and sleep disorder patients (Lee et al., 1991).

Guidelines for scoring the items were: (1) use a clear plastic ruler with millimeter (mm) markings, (2) match zero mark with ruler at zero point of scale, (3) marks in between mm markers were rounded up to the next mm,(4) if a mark crossed the scale, the mark was recorded when the "x" marked the scale, (5) if the mark did not cross the scale, the mark was recorded where the "x" would have crossed the scale. Thirty-six charts (10% of the sample)were randomly selected and an individual not involved in the study and blinded to the results of the original data entry re-entered the data. CRUNCH (version 4) compare module was used to check for reliability of data scoring and there was a 98% reliability.

Sleep Disturbance Scale (SDS)

The SDS was used to assess problems with sleep which range from poor sleep quality, too little sleep, difficulty initiating sleep, midsleep and early awakenings, daytime sleepiness and substances to aid sleep. It consists of 21 items related to frequency with these sleep difficulties in the last week from 0 (never) to 7 (every day). Two items are negatively coded such that the range is from -14 (low disturbance) to 133 (high disturbance) It was used with pregnant patients (Lee & DeJoseph, 1992) who were employed at least 32 hours a week on different shifts and with non-pregnant working nurses (Lee, 1992). Cronbach's alpha was 0.88. Concurrent validity has been established with the DuPuy General Well-Being Schedule vigor scale (r= -0.73, P<.001) and a 100 mm visual analog line where respondents indicated their level of energy (r = 0.60, p<.001).

The LEQ was used to estimate the subjects' stress due to changes in their life in the last three months. It contains 82 items to universal human experiences and included health, work, school, residence, love and marriage, family and close friends, parenting, personal and social events, financial challenges and criminal and legal matters. Events included in the scale have been determined to be of sufficient magnitude to bring about changes in the usual activities of those who experience the event. For each item, the participant is instructed to circle whether a particular event is "good" or "bad" and then to indicate on a 4 point scale the impact the event had on her life ranging from "no effect" to "great effect." Two scores are then attained: (1) negative life events and (2) positive life events. The tool has been used with middle class women of childbearing age (Lee et al., 1994), single mothers from suburban day-care centers and groups of graduate female nursing students (Norbeck, 1984). Test-retest reliabilities have been reported as greater than r=.75. Concurrent validity has been established with the POMS (r=0.34, p<.005), Spielberger State-Trait Anxiety Inventory (r=0.37, p<.01) and Brief Symptom Inventory (Symptom distress, r=0.30, p<.01).

Support Behaviors Index (SBI)

The shortened version of the SBI is an 11-item scale which measures the degree of support received from two categories of significant others: (1) spouse/partner and (2) relatives or friends. Support is defined as multi-dimensional with four subscales: emotional, material, informational and appraisal. Each item is rated from 1 (dissatisfied) to 6 (very satisfied) and scores can range from 6 to 66 in each category. The SBI was tested with couples from the prenatal clinic of a military hospital and childbirth education classes (Brown, 1987). Content validity was established by independent judges and construct validity by factor analysis. The internal consistency reliability was 0.89.

Occupational Fatigue Index (OFI)

The Occupational Fatigue Index (OFI), originally developed by Mamelle and associates (1984) to define physical, psychological and environmental sources of fatigue in working pregnant women, was used to measure occupational demands. It contains five items with definitions (see Table 2.3). Subjects mark whether the item applies to them nor not. This instrument is reliable with retrospective samples in "detrimental working conditions" defined as at least three out of five possible fatigue sources (Mamelle & Munoz, 1987) All or part of this index has been used in numerous ergonomic studies of pregnant women (Teitelman et al., 1990; Meyer & Daling, 1985; Launder et al., 1990). Reliability for this tool (each item on the scale measures a different fatigue source) can only be measured by its ability to predict negative pregnancy outcome such as preterm birth in a similar fashion to other studies. In a study of 1370 American pregnant nurses (Luke et al., 1995), there was a 24% attributable risk of preterm birth due to occupational fatigue, a figure similar to that found by Mamelle and colleagues (1984) in a French regional population.

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Health Habits Scale (HHS)

Good health practices have been shown to have a cumulative effect on health, independent of age and socio-economic status (Taylor et al., 1990). The HHS measures health-related behaviors including exercise, caffeinated and alcoholic beverage intake as well as smoking habits. Exercise is categorized as strenuous or moderate with definitions (see Appendix B) and is measured in terms of minutes per day and times per week to create two exercise scores. Caffeinated beverages, alcoholic beverages, and tobacco use scores were also included and ranged from 0 to 6 for each substance category.

Demographics

A demographic questionnaire was administered during Time I to describe specific socio-economic characteristics of the sample (income, occupation, rank, education), housing (type of residence, number and ages of people living in household, type and number of hours engaged in non-occupational related activities) marital status, ethnicity and age.

Fatigue Diary (Pearson-Byars Feeling Tone Scale)

The fatigue diary was used to measure fatigue severity at six times (upon awakening, noon and at bedtime) over 2 consecutive work days and the women were asked to account for their fatigue when possible. The diary is based on the Pearson-Byars Scale which was developed and used in military populations (Pearson, 1957). There are 6 items with responses ranging from 1 (extremely peppy) to 10 (dead tired) with total possible score from 6 to 60. Validity was established using a fatigue producing apparatus in one group and no apparatus in the control group. There was a significantly greater decline in the experimental group (t=3.80; p=.001) establishing validity of the checklist data. Reliability for consistency in assigning units to categories of fatigue (content analysis) was determined by calculating reproducibility reliability (Waltz et al., 1994). Coefficients of reproducibility of individual items on the scale exceeded or approached the 0.90 acceptance level. The scale was also used in a study involving first trimester pregnant women experiencing fatigue and nausea.(Van Lier et al., 1993). The women were asked to recall their fatigue levels at 6 times from the previous day. The scale was internally consistent (Cronbach's alpha= 0.77). Fatigue scores ranged from 25 to 54 with a mean of 37.6 with 88% of the women reporting that the fatigue was mild to extremely distressing (a single question using a Likert scale ranging from 1, "not distressing," to 5, "extremely distressing").

Time Two Data Collection

Telephone Follow-up

Enrollees were called on a monthly after questionnaire packet administration regarding the number of hours they were working and the type of job at they were employed. Each research assistant kept a personal file of each of the participant and were advised to call the Principal Investigator if she/he had difficulty reaching the participants.

Model Element	Variable	Measure/Instrument
Internal	Depression, Anxiety	Mood State (POMS)
Environmental	Sleep	Sleep Disturbance (SDS)
Demands	Nutritional Status	Hemoglobin at 28 weeks (chart review)
		Prenatal vit., iron (chart review)
	Weight gain	Weight gain (chart review)
	Physical Activity	Exercise - days/wk; minutes/day
		(HHS), leisure/rec hr/wk (D)
	Age	Years (D)
	Alcohol Use	Wine, Beer, Liquor - drinks in last week (HHS)
	Tobacco Use	Pack/day (HHS)
	Caffeine	Coffee, Tea, Cola drinks
		in last week (HHS)
External	Marital Status	Married Single Divorced
Environmental	ivia iai otatas	Senarated (D)
Demands	Social Support	Support Perceived (SRI)
Demands	Housing	# People live with (D)
	Trousing	# Children ≤ 5 years old (D)
		Barracks Shin Ant House (D)
		Bole demands at home (D)
	Occupational conditions	Occupational Demands (OFI)
		Working weekends nights (D)
		Hr/week worked (D)
	Rank	Years in Service (D)
	T WITK	Officer/enlisted rank (D)
	Income	Total Family income/last year (D)
	Education	Years completed (D)
	Life Events	Life Events Percention (LEO)
	Ethnicity	White African-American
		Asian, Latino, Am. Indian (D)
Fatigue	Vitality to Exhaustion	Fatigue severity (VAS-F)
		Mood State, fatigue subscale (POMS)
		Fatigue Diary (Pearson-Byars)
Health Outcome	Preterm Birth	<37 weeks gestation as calculated by
		last menstrual period, ultrasound at 16-
		18 weeks or Dubowitz (chart review)

for Active Duty Military Pregnant Women

HHS - Health Habits Questionnaire, D - Demographics .

Chart Review

Arrangements were made with the Medical Records Departments of each site to pull the prenatal/postpartum chart and infant record of each participant (a copy of each participant's consent form was to be in the maternal chart). Another Research assistant training session was scheduled and data collection was conducted with data entered directly into lap top computers as described in the procedure section of this chapter. Data collection took 3-5 days depending on the number of enrollees at the site.

The variables and instruments in this study and how they relate to the Environmental Demands Model are found on Table 3.3

Data Analysis

Descriptive statistics (frequency, means, standard deviation, ranges) furnished a **Profile of the** fatigued pregnant active duty woman. Outlying data were scrutinized for **Possible miscoding or errors in data entry.** One way analyses of variance was used to **Compare demographic and health characteristics of the four sites, four branches of service and four military occupational specialties.** Factor Analysis of the 18-item VAS-F was **Come to evaluate the conceptual structure of the tool.** Associations between variables of **interest were examined for direction, size and significance and evidence of collinearity. Internal consistency reliability coefficients (Cronbach alpha) were calculated on relevant instruments.** Statistical significance was set at a two-tailed alpha of p<.05.

Hypothesis #1 There will be statistically significant relationships between internal and external environmental demands and the perception of fatigue severity. Pearson correlations were used to determine direction, size and significance between continuous internal and external environmental demand variables and VAS-F scores. Independent samples T-tests were used to determine direction, size and significance between categorical internal and external environmental demand variables and VAS-F scores. Hierarchical linear regression was used to measure relationships between univariately significant predictor variables and fatigue severity. To contrast the contributions of internal and external environmental demands, statistically significant internal demands were placed in the model. Then statistically significant external demand variables were placed in the model. The order of analysis was then reversed to determine the unique contributions of internal demands, controlling for external environmental demands. Stepwise regression was then done to determine the unique contributions of variables for the entire model with fatigue severity as the outcome.

Hypotheses 2.1 to 2.4: There will be a statistically significant difference in the mean perception of fatigue severity and occupational fatigue at 22-26 weeks GA and the incidence of preterm birth and labor in active duty military women. Independent Samples t-tests were used to measure group differences in continuous predictor variables and Chi Square (χ^2) was used for dichotomous predictor categorical variables, and outcome variables of preterm labor and birth. Fatigue severity and occupational fatigue and significant univariate predictors for preterm labor and birth were then placed in a hierarchical logistic regression model. Hypotheses 3.1 and 3.2: The change in the mean perception fatigue severity over two consecutive work days will significantly predict the incidence of preterm labor and birth in active duty women. A repeated measures analysis of variance was performed comparing the fatigue severity scores at six times during two consecutive work days between the preterm and term labor and delivery groups.

Hypotheses 3.3 and 3.4: The change in weekly work hours from 22-26 weeks gestation to delivery date will significantly predict preterm labor and birth in active duty military women. A repeated measures analysis of variance was used to compare hours per weekend occupation at five time points between preterm and term labor and delivery groups.

CHAPTER FOUR

RESULTS

Introduction

Results of the study are presented in this chapter. Of the entire sample of 359, there were 50 women (13.6%) diagnosed with preterm labor, 34 (9.5%) of whom delivered before 37 weeks. The chapter will be organized as follows. First sample characteristics will be described including acceptance, refusal and retention. Second, handling of missing data is reviewed. Third, reliability testing of appropriate instruments used and concurrent and construct validity of fatigue tools were analyzed. Next, assumptions of the statistical model are tested and presented. Fifth, descriptive and bivariate statistics are presented. Lastly, using multivariate analysis, statistically significant relationships between the independent variables, fatigue severity and occupational fatigue and the incidence of dependent variables (preterm labor and birth) are examined.

Acceptance and Refusal Rates

A total of 403 pregnant active duty women from nine OB-GYN clinics of four military medical centers who met criteria were asked to enroll in the study. There were 28 (6.9%) refusals to participate, 7 (1.7%) who left the military after enrollment (due to hardship discharges), 3 (0.7%) who transferred and were not able available for followup, 1 (0.2%) who did not complete her questionnaire packet and 4 (0.9%) who decided to drop out of the study (did not give a particular reason except that they were exercising option of not continuing with study). The final sample consisted of 359 subjects (or 89% of those invited and meeting criteria), 152 from San Diego, 89 from Portsmouth, 60 from David Grant and 58 from Hawaii. In addition, 339 (94%) either mailed back or gave verbal diaries to research assistants and 340 (95%) were successfully followed up regarding their work hours and types of occupations during the last months of their pregnancy. A breakdown of recruitment, diary and telephone follow-up per site is found in Table 4.1.

Table 4.1

Study	y Recruitme	nt Results a	and Dependent	Variable Resu	lts b	y Site
and the local division of the local division						

Site	Number consent- ing to participate meeting criteria	Questionnair packet return	e Diary returned	Telephone P follow-up L returned	reterm Labor %	Preterm Birth %
Ports- mouth	107	89 (83%)	76 (85%)	79 (89%)	19.1	10.1
San Diego	164	152 (93%)	150 (98.6%)	152(100%)	14.5	11.8
Travis	66	60 (90%)	60 (100%)	60 (100%)	13.3	8.3
Tripler	68	58 (82%)	53 (91%)	49 (84%)	5.2	3.4

Missing Data

Missing values from items on subscales (eg. POMS, VAS-F, SBI) were replaced with the mean value of other items on that same subscale when 80% of the items were answered within each of the subscales. Missing data from instruments without subscales were left as missing and omitted from the final analyses, causing the sample size to vary.

Reliability Testing

As internal consistency is sample and instrument specific, Cronbach alpha coefficients were calculated for the POMS subscales, Visual Analog Scale for Fatigue,

Sleep Disturbance Scale, and Support Behavior Index—their subscales as well as their total scales. As reported in Appendix J, these ranged from .80 to .92 for total scales and from .61 to .97 for subscales. With the exception of the POMS confusion subscale with five items ($\alpha = .61$) and POMS tension subscale with five items ($\alpha = .76$), all instruments were within acceptance reliability range (at least 0.80). The tension-anxiety subscale, however, was judged to be acceptable (Waltz, et al., 1991) Reliability coefficients were not obtained for the Life Events Questionnaire or the Occupational Fatigue Index as these measures contained individual items not expected to be internally consistent.

Testing the Validity of Fatigue Instruments

An instrument has validity if it measures what it proposes to measure (Allen & Yen, 1979). In this analysis, both concurrent and construct validity of the fatigue instruments were tested. Since a number of instruments were used in this study to analyze fatigue at the same time, including one which was repeated over a period of time and more convenient to administer than an 18-item instrument, concurrent validity needed to be reported. Concurrent validity refers to a correlation between test and criterion scores when both measurements are obtained at the same time (Waltz et al., 1991). Appendix K shows the concurrent validity analysis of the Profile of Mood States (POMS) Fatigue and Vigor Scales, Visual Analog Scale (VAS) Fatigue and Energy Scales and the Pearson-Byars Scales administered as a fatigue diary over six time periods. VAS-Fatigue was found to have convergent validity with the POMS Fatigue subscale (r=.628, p<.001) and divergent validity with the POMS Vigor subscale (r= - .347, p<.01). Similarly, VAS-Energy had convergent validity with POMS vigor (r= .587, p<.001) and

was negatively associated with the POMS Fatigue subscale (r=-.303, p<.001). The Pearson-Byars diary measurements were also significantly (p<.01) correlated with the POMS fatigue and vigor subscales and VAS fatigue and energy subscales. But none of the correlations was above 0.3.

Construct validity, in contrast, refers to the degree to which a test measures the theoretical trait it was designed to measure (Yen & Allen, 1979). Confirmatory Factor Analysis was performed on the VAS to validate the conceptual structure of the instrument in its ability to measure fatigue and energy, two ends of a continuum of fatigue severity as defined in this study. The identification of the number and types of factors was considered important in fatigue theory development, justifying the use of the two summated visual analog scales into fatigue and energy scores. Factor analysis allowed for testing the relative fit of competing factor models (Floyd & Widaman, 1995).

The 18 item scale was analyzed with the full sample size of 359 (no missing data). Principal components analysis revealed three factors. Before rotation, factor 1 explained 68.2 % of the variance with 8 items loading at .76 or higher. Factor 2 explained 21.8% of the variance with 5 items loading at .66 or higher. Factor 3 contained 3 items explaining 10% of the variance. Generally, three variables per factor are needed to identify common factors (Floyd & Widaman, 1995). However, all 3 factors showed complex loadings with factor 1. "Move body is an effort," for instance loaded on Factor 3 at .42 but also loading on Factor 1 at .68.

With varimax rotation, factor analysis revealed three factors with factor 1 explaining 50.2% of the variance, factor 2, 16% and factor 3, 7.4%. However, the variable "I have a tremendous desire to close my eyes" loaded on Factor 3 at .36 and

Factor 1 at .69. Since the variable did not meet the basic criteria (loading of at least .4) for meaningful loading on Factor 3 (Munro & Page, 1993), this resulted in Factor 3 having only 2 items which is inadequate for identifying common factors.

Therefore, the conclusion for the factor analysis was that two factors explained fatigue and energy for the 18-item scale. Factor analysis was rerun using varimax rotation, utilizing an alpha factor forced into 2 factors. As can be seen in Appendix L, Factors 1 and 2 account for 44.6% and 21.6%, respectively, which meets criteria that the factors should account for at least 50% of the total variance.

Testing the Assumptions of the Statistical Model

Tests were conducted to check for violations of statistical assumptions. Residual scatterplots were examined for outliers, homogeneity of variance, linearity and multicollinearity. Outliers, or data greater than three standard deviations from the mean, were checked to ensure whether the correct value was entered by data coding or entry. Of the twelve major variables measured in this study, five variables had no outliers. The two exercise variables had 8 (moderate exercise) and 10 (strenuous exercise) outliers each, school variable had 6 outliers (those with post-graduate degrees) and the life event change variables had 4 outliers each. Raw data were reviewed and were found to be coded and entered correctly. The decision was made to truncate the exercise variance into one hour periods and keep the other outliers as they appeared to represent extreme cases of the variables (less than 3%).

A review of residual plots showed a homogeneity of variance over a range of dependent variables. The dependent variables of fatigue and energy were plotted against other environmental demands such as age, depression, sleep disturbance, hemoglobin exercise, social support, and life events. There was no evidence of curvilinear relationships between fatigue/energy and the independent variables.

Possible multicollinearity occurs when there is intercorrelation among variables when correlations between independent variables is greater than 0.80 (Glantz & Slinker, 1990). An examination of correlation matrices (see Tables 4.20 and 21 later in this chapter) showed that most correlations between variables were found between -.36 to .64. Not shown in the tables are the following notable exceptions. First, hemoglobin and hematocrit were highly correlated with each other (r=.918, p<.001) as expected. Social behavioral index (SBI) (measuring social support) and its partner subscale also approached redundancy (r=.820, p<.001). Consequently, only hemoglobin (not as affected by hemodilution) and the total SBI were used in subsequent analysis.

Based on these analyses, the assumptions of homogeneity of variance, linearity and independence were met for this study.

Demographic Characteristics

Demographic characteristics are presented in Table 4.2. The majority of the participants were White, under 25 years of age and had a twelfth grade education. Most were enlisted women in the Navy and 9% were officers. An explanation of the implications of military rank and the actual names of enlisted and officer ranks in the

	<u>Mean</u>	<u>SD</u>	<u>Range</u>	Numt	er (Percent)
Age in years	23.93	4.8	18 - 40		
Education in years	12.92	1.6	11 - 20		
Education in levels	<u>8</u>				
Below High	h School			1	(0.3)
High Schoo	ol Graduate			232	(64.6)
l year past	high school			38	(10.6)
2 years pas	t high school			43	(12.0)
5 years pas	t nign school			4	(1.1)
Graduate S	chool and beyo	ond		17	(4.8)
Marital Status					
Married				219	(61.0)
Not marrie	d (live with na	rtner)		51	(01.0) (14.2)
Never marr	ried			66	(18.4)
Divorced				11	(3.1)
Separated				12	(2.2)
Housing Situation					
Base Quart	ers			113	(31.5)
Civilian Ar	partment			163	(45.4)
Civilian De	etached house			83	(23.1)
Total Number of P (Not including resp	ersons in Hou: pondent)	sehold			
Live alone				60	(16.7)
1				189	(52.6)
2				69	(19.2)
3				28	(7.8)
4 or more				13	(3.7)
Parity					
Nulliparity				241	(67.1)
1				84	(23.4)
2				28	(7.8)
3				6	(1.7)

Table 4.2 Demographic Characteristics of Respondents (n=359)

Table 4.2 Continued

Demographic Characteristics of Respondents (n=359)

	Number (Percent)
Presence of Children <5 years of age	91 (25.3)
Presence of Children <3 years of age	71 (19.8)
Military Occupation Specialty	
Moderate Stress	230 (64.1)
Mental Stress	18 (10.6)
Exposure to Hazardous Material	31 (8.6)
Physical Stress	80 (22.3)
Military Rank (eg. equivalent Navy ranks)	
(Enlisted ranks)	328 (91.4)
E-1 (eg. Seaman recruit)	5 (1.4)
E-2 (eg. Seaman apprentice)	59 (16.4)
E-3 (eg. Seaman)	99 (27.6)
E-4 (eg. Petty Officer Third Class)	104 (29.0)
E-5 (eg. Petty Officer Second Class)	43 (12.0)
E-6 (eg. Petty Officer First Class)	11 (3.1)
E-7 (eg. Chief Petty Officer)	7 (1.9)
(Officer ranks)	31 (8.6)
O-1 (eg. Ensign)	4 (1.1)
O-2 (eg. Lieutenant Junior Grade)	3 (0.8)
O-3 (eg. Lieutenant)	13 (3.6)
O-4 (eg. Lieutenant Commander)	8 (2.2)
O-5 (eg. Commander)	3 (0.8)
Branch of Service	
Air Force	55 (15.3)
Army	30 (8.4)
Coast Guard	6 (1.7)
Marines	7 (1.9)
Navy	259 (72.1)
Public Health Service	2 (0.6)

Table 4.2 Continued

.

Preterm Birth

Demographic Characteristics of Respondents (n=359)

Number	(Percent)

(9.5)

34

Family Income in 1995 in dollars

Under 3,000	12	(3.4)
3,500-4,999	6	(1.7)
5,000-6,999	5	(1.4)
7,000-9,999	11	(3.1)
10,000-14,999	79	(22.1)
15,000-19,999	48	(13.4)
20,000-24,999	46	(12.8)
25,000-29,999	27	(7.5)
30,000-34,999	35	(9.8)
35,000-39,999	25	(7.0)
40,000-49,999	27	(7.5)
50,000-59,999	17	(4.7)
60,000-69,999	6	(1.7)
70,000 or more	14	(3.9)
Ethnicity		
African American	90	(25.1)
Asian	8	(2.2)
Latino	30	(8.4)
Native American	5	(1.4)
White	222	(61.8)
Other	4	(1.1)
Site of Enrollment		
Portsmouth (Virginia)	89	(24.8)
San Diego (Southern California)	152	(42.3)
Travis (Northern California)	60	(16.7)
Tripler (Hawaii)	58	(16.2)
Preterm Labor	50	(13.9)

different services can be found in Appendix E. More than half were married, had at least one other person living with them, 25 % had children less than 5 years of age, 67.1% were nulliparous, only 17% had previous therapeutic abortions and most lived in apartments. All were employed, with the majority at 22-26 weeks in the Military Occupational Specialty (MOS) category 1, mild-moderate stress, or category 4, physical stress. Most had family incomes higher than \$20,000 a year.

Internal Environmental Demands Descriptive Statistics

Mood and Sleep

Depression and anxiety scores averaged 4.16 (SD=4.03) and 5.13 (SD=3.67) respectively out of POMS subscales of 0 - 20. Overall sleep disturbance mean was 48.9 (SD=15.78) with the disturbances having the highest means include "wake-up during sleep" (5.1, SD=2.13), "feel sleepy at work" (4.4, SD=2.13) and "get too little sleep" (4.1, SD=2.19). With reverse coding (meaning that the statement was scored in the opposite direction of what was marked—indicated more sleep disturbance with higher scores), there were similar mean scores for not feeling alert at work (4.45, SD=1.68), dissatisfaction with sleep quality (4.34, SD=1.90) and not feeling rested upon awakening (4.16, SD, 1.84). Few took substances to go to sleep(see Table 4.3).

Nutritional Status/Substance Intake and Weight Gain

Hemoglobin, used as a marker for dietary intake, ranged from 7.2 to 14.6. Only 29 (7.6%) had a hemoglobin level that could be defined as maternal anemia (less than 10 g/dl). Three hundred eighteen (88.6%) of the participants were taking prenatal vitamins upon entry to labor and delivery. Of the group surveyed for taking iron, 114 (78.1%) were taking iron in tablet form. .

Mean Scores on Study Variables: All Subjects (n=359)

Variable (Instrument)	No. (%)
Internal Environmental Demands (cont	inued)
Moderate Exercise (Health Habits Ques in minutes/week	stionnaire)
0	235 (65.5)
1-60	62 (17.3)
61-120	35 (9.7)
121-180	18 (5.0)
>180	8 (2.2)
Strenuous Exercise (Health Habits Que in minutes/week	stionnaire)

0	165 (46.0)
1-60	74 (20.6)
61-120	53 (14.8)
121-180	31 (8.6)
>180	36 (10.0)

No Moderate or Strenuous Exercise (Health Habits Questionnaire)

Total weight gain in pregnancy averaged 36.75 pounds (SD=14.24) with a range of a negative net loss of weight during pregnancy of -3.2 pounds to a total gain of 90 pounds (see Table 4.3).

Substance Use

Most (345, 96.11%) of the pregnant active duty women at 22-26 weeks denied taking alcohol. The majority consumed caffeined drinks more than 2 times a week. Ten percent (37) of the women still smoked at 22-26 week gestation, with 30% (107) having quit during the earlier part of their pregnancy. Of those who were still smoking, only three (0.8%) smoked more than one pack per day (see Table 4.3).

<u>Exercise</u>

As seen in Table 4.3, 123 women (34.5%) reported participating in moderate physical activity in the past week compared to 194 (54%) in strenuous activity which included brisk walking. Since this was an open-ended question, the raw data indicated a wide range of answers from no exercise to 40 hours a week. Hence, the data were truncated into five one-hour intervals. While exercise was not a mandatory requirement for these active duty women, most of them (257, 72%) did some exercise in pregnancy.

External Environmental Demands Descriptive Statistics

Social Support

As seen in Table 4.4, the mean social support score for this sample was relatively high at 103.7 (SD=20.1) on a scale of 0 to 132. Under the partner and friend/relative subscale, the item with highest means relating to support were "let's me know that he/she will be around if I need assistance. However, the next highest mean was "allows me to talk about private things" for the partner and "takes me seriously when I have concerns" for the friend/relative.

Housing Conditions

Originally, the non-occupational roles were measured in terms of hours per week. Like the exercise variable above, this question was open-ended and the raw data ranged from 0 to 347 hours that the women put into their household activities over and beyond what they did for work (more hours were allotted for days off and weekends). Hence, each of the six activities was changed to a dichotomous variable. Then the number of roles were totaled rather than the amount of time that was spent by the participant in each role. Based on this criteria, average number of roles amounted to 3.36 (SD=1.1) with the most common roles including homemaking, leisure activity and the maintenance of adult relationships. The least common role was volunteering (55, 15.3%).

Occupational Conditions

On the Occupational Fatigue Index (OFI), a composite score of five possible sources of occupational fatigue, participants averaged 1.16 (SD=.94). The most common source of occupational fatigue was mental stress, followed by posture, and environmental exposures. In contrast, very few women worked on industrial machines. Part of the OFI was an estimation of weekly commute hours. Most respondents averaged 4.03 hours (SD=4.24) a week and 318 (88.6%) drove a car to go to work. Twenty-three (6.4%) walked to work. Average weekly work hours were 42.66 (SD=6.88) at 22-26 weeks gestation with a range of 13 to 66 hours a week. Most (242, 67.4%) were not satisfied with their present job, but fewer had jobs that required working on weekends and at night.

Table 4.4

Mean Scores on Study Variables: All Subjects, External Demands(n=359)

Variable (Instrument)	Mean SD		Sample Instrument Range Range		No. (%)				
External Environmental Demands									
Social Behavior Index(SBI)	103.7	20.1	43 - 132	22 - 132					
SBI Partner	51. 78	15.37	11-66	11 - 66					
Share experiences	4.35	1.57	1 - 6	1 - 6					
Keep up Morale	4.68	1.61	1 - 6	1 - 6					
Help in Pinch	4.86	1.57	1 - 6	1 - 6					
Shows interest in me	4.62	1.64	1 - 6	1 - 6					
Special things for me	4.45	1.74	1 - 6	1 - 6					
Personal Talk	5.01	1.53	1 - 6	1 - 6					
Appreciates me	4.64	1.62	1 - 6	1 - 6					
Tolerates up/down	4.72	1.61	1 - 6	1 - 6					
Takes me seriously	4.79	1.52	1 - 6	1 - 6					
Understand situation	4.52	1.52	1 - 6	1 - 6					
Assists me	5.09	1.48	1 - 6	1 - 6					
SBI Relative, Friend	52.26	11.41	11 - 66	11 - 66					
Share experiences	4.60	1.25	1 - 6	1 - 6					
Keep up Morale	4.81	1.21	1 - 6	1 - 6					
Help in Pinch	4.80	1.26	1 - 6	1 - 6					
Shows interest in me	4.59	1.28	1 - 6	1 - 6					
Special things for me	4.47	1.40	1 - 6	1 - 6					
Personal Talk	4.78	1.34	1 - 6	1 - 6					
Appreciates me	4.62	1.30	1 - 6	1 - 6					
Tolerates up/down	4.73	1.30	1 - 6	1 - 6					
Takes me seriously	4.94	1.16	1 - 6	1 - 6					
Understand situation	4.76	1.25	1 - 6	1 - 6					
Assists me	5.16	1.18	1 - 6	1 - 6					
Non-Job Roles (Health Habit	s Quest	ionnair	e)						
Homemaking			,		333(92.8)				
Student					95(26.5)				
Volunteer					55(15.3)				
Parenting					109(30.4)				
Leisure					307(85.5)				
Adult Relations					307(86.0)				
Total Number of Roles	3.36	1.1	0 - 6	0 - 6					

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Variable (Instrument)	Mean	SD	Sample Range	Instrument Range	No. (%)
External Environmental Dem	ands				
Occupational Fatigue (Occupational Fatigue Index) Posture Industrial Machine Physical Exertion Mental Stress Environment	1.16	.94	0-5	0-5	110(31) 4(1.1) 28(7.8) 199(55.4) 78(21.7)
Commute hours	4.03	4.24	0-40		
How Commutes Car Walk Bus Other					318(88.6) 23(6.4) 8(2.2) 10(2.8)
Hours of Work	42.66	6.88	13 -66		
Not Satisfied with Work					242(67.4)
Works on Weekends					170(47.4)
Works at Night					131(36.5)
Life Events Change (Life Events Questionnaire)					
Positive Life Events Negative Life Events	14.29 10.78	10.28 9.6	0 - 68 0 - 53	0-82 0-82	

Table 4.4 -continuedMean Scores on Study Variables: All Subjects (n=359)

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Duty (work over and beyond the regular work day with no overtime paid) was required for 130 (36.4%) of the respondents.

Life Event Change

Respondents averaged slightly more positive life events (14.3, SD=10.28) than negative life events (10.8, SD=9.6); 304 respondents noted pregnancy to be a major life change, 290 (96.4%) of which noted it to be a positive event. The next most common life change was a change in sleep habits, with 186 (75.6%) rating it as a negative event. A third change was that of eating habits, most of whom considered it positive. The other major changes had to do with work conditions (hours, responsibilities, troubles with coworkers), changes in relationships with partner either due to closeness or separation due to work and social/recreational and financial changes.

Fatigue Severity Outcomes Descriptive Statistics

The fatigue severity measurements are described in Table 4.5. The mean score of the VAS-F was 44.28 (SD=21.3, range 0 -100). Mean total score of the VAS-Fatigue, which was the basis of the T-tests and regression calculations, was 575.7 (SD=283.4, range 0-1240). There were 60 (18%)respondents with a high amount of fatigue defined as a VAS-F score of over 850. If higher fatigue was defined as roughly the midpoint of the VAS-F (660), 1553 (42%) of the respondents experienced a high amount of fatigue. The mean score of the VAS-energy was 38.46 (SD=19.48, range 0-100). Mean total score of the VAS-energy, which was the basis of the T-tests and regression calculations, was 192.3 (SD=94.4, range 0-500). There were 95 (26.5%) respondents reported a high amount of energy as defined by a VAS-F score of over 250.

 Mean Scores on Study Variables:
 All Subjects, Fatigue Tools (n=359)

					Mean		
Variable (Instrument)		Mean	SD	Sample	Instrument	Diff-	t-test
				Range	Range	erence	(p-value)
Visual	Analog Scale-Fatigue	44.28	21.30	0 - 100	0 - 100		
	Tired	52.80	27.30	0 - 100	0 - 100		
	Sleepy	49.90	28.90	0 - 100	0 - 100		
	Drowsy	43.40	29.50	0 - 100	0 - 100		
	Fatigue	47.60	28.80	0 - 100	0 - 100		
	Worn out	47.60	29.20	0 - 100	0 - 100		
	Bushed	46.00	28.20	0 - 100	0 - 100		
	Exhausted	49.40	28.80	0 - 95	0 - 100		
	Keep Eyes Open	34.50	27.40	0 - 100	0 - 100		
	Chore Moving Body	37.40	25.80	0 - 99.5	0 - 100		
	Chore Concentrating	35.20	25.60	0 - 100	0 - 100		
	Chore Conversation	24.30	21.30	0 - 96.5	0 - 100		
	Desire Close Eyes	49.70	27.20	0 - 100	0 - 100		
	Desire Lie Down	57.30	28.50	0 - 100	0 - 100		
Visual	Analog Scale-Energy	38.46	19.48	0 - 100	0 - 100		
	Energetic	36.60	23.60	0 - 100	0 - 100		
	Active	38.80	23.60	0 - 100	0 - 100		
	Vigorous	30.30	20.80	0 - 100	0 - 100		
	Efficient	47.00	23.50	0 - 100	0 - 100		
	Lively	39.40	21.80	0 - 100	0 - 100		
Pearso	n-Byars (Diary)						
	Day 1 Morning	4.73	2.45	0 - 10	0 - 10		
	Day 1 Midday	4.56	2.24	0 - 10	0 - 10		
	Day 1 Evening	6.56	2.32	0 - 10	0 - 10		
	Day 2 Morning	4.27	2.48	0 - 10	0 - 10		
	Day 2 Midday	4.28	2.20	0 - 10	0 - 10		
	Day 2 Evening	6.37	2.48	1 - 10	0 - 10		
	Morning Average	4.50	2.17	0 - 10	0 - 10		
	Midday Average	4.42	1.99	0 - 10	0 - 10		
•	Evening Average	6.47	2.15	1 - 10	0 - 10		
	Morning-Midday Ave	erage D	ifferenc	æ		.08	.665
						(p	⊨.507)
	Evening-Morning Av	erage D	Differen	ce		1.97	14.41
						(p	<.001)

The Pearson-Byars Feeling tone diary measured fatigue morning, midday and night over two consecutive work days. All the scores on day one were correlated with their corresponding score on day two(see Appendix K). Mean fatigue scores were highest in the evening and paired t-test calculations showed a significant difference between evening and morning fatigue as shown on Table 4.5.

Bivariate Relationships Among Variables

This section contains comparisons by site and branch of service and military occupational specialty (MOS). Pearson correlations among continuous variables and χ^2 relationships among categorical variables are described. Independent t-tests for continuous variables and their relationship to dichotomous outcomes of pregnancy (term and preterm labor and birth) are also described.

Study Sites and Sample Characteristics

Of the four sites from which subjects were recruited, six branches of services were represented and collapsed to 3 branches (Army, Navy, Air Force) plus other (Marines, Coast Guard, Public Health System). Since the four military occupational specialty codes might well serve different sectors of the active duty military population, they were compared with each other on key demographic and fatigue outcome characteristics by a series of one-way analyses of variance (see Appendix M).

Among the research sites, the Travis Air Force Base (AFB) site showed statistically significantly higher age, education and rank than San Diego. Clinically, the difference between ages 25 and 23, 13.6 years of school versus 12.7 years of school and the difference between E-4 and E-5 is not meaningful. On the other hand, there were no đ

statistically significant differences among sites for ethnicity, fatigue severity and the outcome measures of preterm labor and birth.

Similarly, among branches of services, the Air Force showed statistically significant higher education and rank than the Navy. In the MOS physical stress group, there was a statistically higher, but not clinically relevant, education level than in the moderate stress MOS group. However, there were nearly twice as many non-white participants in the Army (most of whom were enrolled from Tripler) than the other services (χ^2 =7.941, p=.047).

Since there were significant clinical and statistical differences among subjects from the various sites and branches, these variables were further analyzed using Chi square analysis. Ethnicity and site were not significantly related to preterm labor $(\chi^2=.891, p=.345 \text{ and } \chi^2=5.721, p=.124, \text{ respectively})$ or preterm birth $(\chi^2=.507, p=.477$ and $\chi^2=3.584, p=.310$, respectively). Hence, site and ethnicity were not included in the hierarchical regression models.

Interrelationships Among Variables For Fatigue

This section contains the direction, strength and statistical significant of the bivariate statistical analysis between fatigue and energy with both VAS and POMS and statistically significant independent variables as listed in Appendices N to U. Only variables reaching significance of p<.01 are listed.

Fatigue, as measured by the Visual Analog Scale-Fatigue (VAS-F) (see Appendix N), was positively and significantly associated with depression (r=.37, p<.001), anxiety (r=.33, p<.001), sleep disturbance (r=.57, p<.001), and negative life events (r=.29,

p<.001). VAS-F was weakly and negatively associated with hemoglobin (r= -0.16, p=.01. The only categorical independent variable reaching statistical significance (p<.01) with VAS-F was satisfaction with the work situation (t=2.383, p=.01) as shown in Appendix O.

Fatigue, as defined by the POMS fatigue subscale (see Appendix P) was also positively and significantly associated with depression (r=.47, p<.001), anxiety (r=.51, p<.001), sleep disturbance (r=.52, p<.001) and negative life events (r=.32, p<.001). Similarly, it was also negatively associated with number of role demands (r= -0.37, p=.01). Unlike the VAS, POMS-fatigue was also positively related to the occupational fatigue index (r=.17, p=.001) Like VAS-F, the only categorical variable reaching significant (see Appendix Q) was satisfaction with the work situation (t=4.423, p=<.001).

Energy, as defined by the VAS-Energy (see Appendix R), was positively and significantly related to age (r=.22, p<.001), social support (r=.21, p<.001), number of role demands (r=.239, p<.001), and income (r=.19, p<.001). It was negatively associated with depression (r= -0.31, p<.001), anxiety (r= -0.15, p<.001), sleep disturbance (r= -0.39, p<.001) and negative life changes (r= -.35, p<.001). As shown in Appendix S,VAS-E was related to being married (t=2.366, p=.019), homemaking (t= -2.488, p=.013), student role (t=-2.408, p=.017). volunteering (t=-2.568, p=.011), and adult relations (t=-3.013, p=.003). As with the VAS-F, the role demand items were not included in the regression model due to redundancy with role demand variable.

Energy, as found with the POMS vigor subscale (see Appendix T), was positively associated with strenuous exercise (r=.19, p<.001), social support (r=.15, p=.01), role

demands (r=.155, p=.001) and income (r=.18, p=.01). As in VAS-energy, it was negatively related to depression (r= -0.24, p<.001), anxiety (r=- 0.14, p<.001), sleep disturbance (r= -0.43, p<.001) and negative life events (r=-0.34, p<.001). The one significant categorical variable (see Appendix U) included a difference in VAS-E scores between the White ethnic group and the non-White ethnicities (t=2.627, p=.009).

A decision was made to use the VAS-F and VAS-energy as the outcome variables for the multivariate model due to the following reasons: (1) VAS-F was moderately correlated to POM-fatigue (r=.61, p<.001) as was VAS-energy related to POM-vigor (r=.59, p<.001, (2) VAS-fatigue and VAS-energy were more internally consistent (α =.93 and .91, respectively) than the POM-Fatigue and the POM-vigor (both have α =.87), (3) VAS-fatigue is based on 13 items as opposed to 5 items on the shortened version of the POM-fatigue, (4) the Pearson-Byars scale is more a uni-dimensional scale and may not reflect the performance and sleep-related issues reflected in the VAS subscales, (5) compared to the VAS-F, the POMS-F was more highly correlated with the POMS-D (r=.47) and (6), most significantly, there is a greater inverse relationship between VAS-F and VAS-E (see Appendix K) than between the POMS-F and POMS-V. Hence, it was decided that the VAS-F was the more valid estimate of fatigue severity in this sample of military women.

Pearson Product Moment Corr	elations Betwe	en Visual	Analog (Scale (VAS)-	Fatigue an	d Significa	unt Contir	nuous Univari	ate Internal
and External Environmental D VAS-F	<u>emands (n=35</u> Depression	<u>9)</u> Anxiety	Sleep Disturb.	Hemoglobin 28 weeks	Caffeine	Social Support	Role Demand	Negative Life Events	Occupation- al Fatigue Index
VAS-Fatigue	.37**	.33**	.57**	16*	.12	11	16	.29**	.079
Depression		.64**	.4]**	-11	.066	30**	17*	.54**	.093
Anxiety			.38**	072	.094	14*	11	.41**	.083
Sleep Disturbance				093	.086	216**	15	.41*	.22*
Hemoglobin 28 weeks					074	.054	.12	-11	.138
Caffeine						11	.003	.11	.017
Social Support							.041	36**	013
Role Demands								15	.048
Negative Life Events									.134
Occupational Fatigue Index									0.1
Note: *p<.01 **p<.001									

Table 4.6

Table 4.6 and Appendix V show the intercorrelations between independent variables to enter the multivariate model, which, as pointed out earlier in this chapter, confirm that multicollinearity is not a concern for this particular analysis.

Hypotheses Testing for Fatigue Description

In this section, data will be presented in order to answer Hypothesis #1 of this study which was to describe the relationship between internal and external environmental demands and the perception of fatigue severity.

Hypothesis testing for this aim was accomplished by a series of hierarchical and stepwise multiple linear regressions utilizing the significant univariate variables identified in the previous section where both the POMS and VAS were utilized as outcome variables. The following sequences with VAS-fatigue and VAS-energy as dependent variables were used to: (1) enter significant internal environmental demands to attain statistical control for their effects followed by significant external environmental demands to determine their unique contribution to predicting fatigue, (2) enter significant external environmental demands first to control for their effects followed by internal environmental demands to determine their unique contribution to fatigue and (3) enter all significant independent variables into a stepwise multiple regression. The advantage of stepwise regression is that it is useful in screening large numbers of possible independent variables without serious collinearity (Glanz & Slinker, 1990). Variables are eliminated as they become redundant with the information of several variables enteredleading to parsimonious models which can be contrasted with earlier hierarchical models.

Table 4.7 describes the two-step hierarchical regression analysis where internal environmental demands are entered first in order to predict fatigue. Internal demands,

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particularly depression and sleep disturbance, explain 35.9% of the variance [F (5, 354)= 39.185, p<.001]. After controlling for internal demands, none of the external environmental demands provided a significant contribution to fatigue. Total variance explained by both steps was 36.9%[F(11, 348)=17.36,p<.001].

In Table 4.8, external environmental demands, when forced into the model at step 1, account for 6.8% of the variance in predicting fatigue [F (6, 353)=6.063, p<.001]. After controlling for external environmental demands, entering depression and sleep disturbance accounted for an additional 25.7% of the variance[F(11,348)=17.96, p<.001]. All univariately significant internal and external environmental demands were entered into stepwise linear regression (see Table 4.9) with VAS-fatigue as the dependent variable. The analysis indicated that 34.5% of the overall variance in fatigue severity was explained by predictor variables. Sleep disturbance accounted for 31.9% of the variance [F(1.345)=161.313, p<.001] and depression accounted for 2.7% [F(1,344)=13.943, p<.001]. Sleep disturbance was determined to be a strong predictor of fatigue scores.



Table . <u>Hierar</u>	4.7 chical Linear Multiple Regression Analysis	: Depende	nt Variab	le - VAS-F(n= 3	159), Contre	ol Internal Den	<u>nands</u>	
Step	Variable	df	Beta	Cum R ²	Sr ²	R ² Chg	F-Value	p-value
_	Internal Environmental Demands	S		359		.359	39.185	0000
	Depression	1	.122		800.		4.533	.034
	Anxiety	1	.057		.002		1.002	.318
	Sleep Disturbance	I	.484		.187		102.293	000
	Hemoglobin at 28 weeks	1	072		.005		2.779	960.
	Caffeine	1	.068		.005		2.512	.114
2	External Environmental Demands	9		.369		.010	17.360	0000
	Social Support	1	.052		.002		1.190	.276
	Role Demands	I	050		.002		1.219	.270
	Negative Life Events	1	006		.00002		.0125	116.
	Satisfaction with Work	1	.012		1000.		.063	.802
	Occupational Fatigue Index	-	052		.002		1.236	.267
	Tobacco	1	-000-		.0000		.0433	.835
	Works on Weekends	1	.012		.000		.0671	.796

Step	Variable	df	Beta Cum R ²	sr ² R ² Chg	F-Value	p-value
-	External Environmental Demands Social Support	6 1	.112 016	.0002	6.063 .0823	.0000 .774
	Role Demands	1	135	.0179	6.781	.010
	Negative Life Events	1	.248	.0502	18.983	.001
	Satisfaction With Work	1	.068	.004	1.318	.219
	Occupational Fatigue	1	007	.00004	.0169	.896
	Tobacco	1	047	.002	.8082	.369
	Works on Weekends	1	.043	.002	.6256	.429
2. In	tternal Environmental Demands Depression	5 1	.369 .132	.2 <i>57</i> .009	17.965 4.8092	.0000 .029
	Anxiety	1	.045	.001	.5959	.441
	Sleep Disturbance	1	.495	.178	95.2771	000
	Hemoglobin at 28 weeks	1	081	900.	3.240	.073
	Caffeine	1	.069	.0044	2.4056	.122

Table 4.8 Hierarchical Linear Multiple Regression Analysis: Dependent Variable - VAS-F(n= 359),Control External Demands

 Table 4.9

 Stepwise Linear Multiple Regression Analysis: Dependent Variable - Visual Analog Scale

 Fatigue (n= 359)
 Variable*
 Beta
 Cum R² R² Chg
 F-Value
 df
 p-value

Variable*	Beta	Cum R ²	R ² Chg	F-Value	df	p-value
Sleep Disturbance	.564	.319	.319	161.313	1,345	.0000
Depression	.180	.345	.027	13.9426	1,344	.0000

*.05 limit reached after 2 of the variables were entered

In a separate analysis, univariately significant internal environmental demands were entered into a hierarchical linear regression analysis with VAS-energy as the dependent variable. Internal demands (depression, anxiety, sleep disturbance, age and strenuous exercise) explained 23.5% of the variance in energy as shown in Appendix W. After controlling for internal demands, role demands and negative life events only added 3% of the variance. This analysis accounted for an overall variance of 30.5% [F(14,345)=0.24, p<.001].

In Appendix X, external environmental demands are initially entered into linear regression analysis. In addition to role demands and decreased negative life events, social support uniquely contributed to VAS-energy, accounting for 7.9% of the total 20% explained by this model [F(9,350)=9.208, p<.001]. After controlling for external demands, anxiety, decreased sleep disturbance, age and strenuous exercise still uniquely accounted for 10.2% of the variance. Overall variance of 30.5%[F(14, 345)=10.24, p<.001] was explained by the predictor variables.

All significant univariate internal and external environmental variables were entered into a stepwise linear regression analysis with VAS-energy as the dependent variable as shown in Table 4.10. Decreased sleep disturbance, negative life events and increased age, role demands and strenuous exercise accounted for 27.5% of the variance in energy. The two strongest predictors were low sleep disturbance [F(1,340)=74.1321, p<.001] and low negative life events $[F\{1,339\}=18.238, p<.001]$

 Stepwise Linear Multiple Regression Analysis: Dependent Variable - Visual Analog Scale-Energy (n= 359)

Variable*	Beta	Cum R ²	R ² Chg	F-Value	df	p-value
Sleep Disturb	423	.179	.179	74.1321	1,340	.0000
Negative Life Events	225	.221	.042	18.238	1,339	.0000
Age	.173	.250	.029	13.163	1,338	.0000
Role Demands	.123	.263	.013	6.052	1,337	.014
Strenuous Exercise	.108	.275	.012	5.377	1,336	.021

In summary, the hypothesis for Aim #1 was supported in that there was a statistically significant relationship between some internal and external environmental demands and the perception of fatigue severity. The internal demand, sleep disturbance, was a significant predictor in both energy and fatigue models, even when external demands were controlled. Internal environmental demands accounted for more of the variance than external environmental demands. A respecified illustration of the Environmental Demands Model for active duty military women is found in figure 4.1.

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Figure 4.1: Respecified Model of Environmental Demands for Fatigue in Pregnant Military Women

Internal Environmental Demands Depression Poor Sleeping Patterns Age Exercise

Vitality ↑ → Fatigue ← ↓ Exhaustion External Environmental Demands

Housing (Role Demands) Negative Life Events

Interrelationships Between Variables For Predicting Preterm Labor and Birth

This section contains the direction, strength and statistical significance of the bivariate statistical analysis of internal and external environmental demand variables capable of independently explaining two dichotomous pregnancy outcomes, preterm labor and preterm birth. Hypotheses 2.1 to 2.4 refer to variables measuring fatigue severity and occupational fatigue as the primary independent variables of interest. However, the importance of avoiding model misspecification due to omission of additional information necessary to predict the dependent variables (Glanz & Slinker, 1990) requires the analyses of other variables derived from data collected to predict

	T <u>erm Labor</u>		Preterm Lal	<u>100</u>		
Variable (Instrument)	Mean (SD)	Sample Range	Mean (SD)	Sample Range	Instrume Range	nt T- Test
Fatigue (POMS)	9.7 (4.7)	1 - 20	8.9 (5.3)	0 - 20	(0 - 20)	-1.010 (p=.313)
Fatigue (VAS-Fatigue)	586.7 (280.6)	0-1230	508.7 (294.4)	60-1240	(0-1300)	1.807 (p=.072)
Fatigue Pearson-Byars ((Evening 1 st day	6.58 (2.3) PB) /) ^a	0 - 10	6.41 (2.2)	0- 10	(0 -10)	.3.97 (p=.691)
Energy (POMS-V)	6.8 (3.6)	0 - 17	6.2 (4.0)	0 - 16	(0 - 20)	-1.138 (p=.256)
Energy (VAS-Energy)	192.5 (96.2)	10-500	191.4 (105.8)	20-440	(0 - 500)	076 (p=.939)
Variable	<u>Term Lat</u> Number	<u>oor</u> (Percent)	<u>Pret</u> Num	erm Labo ber (Perce	r ent)	χ²
Severe Fatigue (VAS-Fatigue dichotomized)	>660 = 13 0-660 = 1	8 (44.7) 71(55.3)	15 (3 35 (7	30.0) 70.0)		3.782 (p=.052)

Table 4.11 Fatigue Severity Measures For Preterm Labor (n = 359)

^aChosen because measurement of most fatigue and not significantly different (t=1.671, p=.096) from fatigue evening day 2
	Term Birth		Preterm Bir	Preterm Birth			
Variable (Instrument)	Mean (SD)	Sample Range	Mean (SD)	Sample Range	Instrument. Range	T- Test	
Fatigue (POMS)	9.6 (4.6)	0 - 20	9.3 (5.7)	1 - 20	(0 - 20)	.25 (p=.801)	
Fatigue (VAS)	579.0 (283.4)	0-1240	544.1 (285.8)	60-990	(0-1300)	.71 (p=.477)	
Fatigue (PB) ^a	6.47 (2.17)	0 - 10	6.5 (1.98)	0 - 9	(0 - 10)	074 (p=.941)	
Energy (POMS)	6.7 (3.6)	0 - 17	6.3 (4.3)	0 - 16	(0 - 20)	.15 (p=.879)	
Energy (VAS)	192.6 (96.5)	0-500	190.1 (108.4)	2 - 44	(0 - 80)	.14 (p=.888)	

Table 4.12 Internal and External Environmental Fatigue Severity Measures

^aChosen because measurement of most fatigue and not significantly different from fatigue evening day 2

fatigue severity. Since the sample size (n=359) was not large enough to begin the multivariate model with all possible variables, each variable was tested independently for association with preterm labor and birth using appropriate univariate analysis (Hosmer & Lemeshow, 1989). The t-test was used for continuous variables since its p-value is of the same order of magnitude as that of the Wald statistic (β coefficient/standard error) or the likelihood ratio test from logistic regression. The Pearson χ^2 test is also asymptotically equivalent to the likelihood ratio test and therefore can be used with dichotomous variables. Variables for the multivariate model were selected based on statistical significance of 0.25. Hosmer and Lemeshow (1989) suggest that use of a more traditional level (such as 0.05) often fails to identify variables known as important. On the other hand, variables of questionable importance may also be included during model building which requires a critical review, including scientific relevance, consideration of confounders, interactions and goodness-of-fit, before a decision is reached regarding the final model.

Hypothesis Testing for Preterm Labor and Birth Prediction

In this section, data will be presented in order to answer hypotheses 2.1 to 2.4 of this study which was to predict the incidence of preterm labor and then preterm birth from fatigue and its correlates.

Predictors of Preterm Labor

Taking into consideration the proposed model building strategy, the following variables were selected for entry into the logistic regression equation for the dichotomous dependent variable, preterm labor. Anxiety (t= -1.353, p=.177), sleep disturbance (t = -2.531, p=0.12), total weight gain considering gestation (t= -1.516, p=.130), and caffeine intake (t=3.623, p=.057) were significant predictors of preterm labor (see Appendix Y). Among external environmental demands (see Appendix Z), the following variables met screening criteria: work at night (χ^2 =1.414, p=.234), posture subscale of Occupational Fatigue Index (χ^2 = 2.394, p=.122), negative life events (t=1.324, p=.186), education (t=1.329, p=.185) and officer rank (χ^2 =6.458, p=.011). Total weight gain and body mass index not considering gestation were statistically significant, but due to the bias of duration of gestation already discussed in Chapter 2, these variables were not included in the model.

Among the fatigue severity variables (see Table 4.11) VAS-fatigue also met criteria for entering the model (t=1.807, p=.072). Total VAS-fatigue scores were

dichotomized at the median (greater than 660 mm. Analysis of a dichotomized VASfatigue in predicting preterm labor improved statistical significance (Pearson $\chi^2 = 3.782$, p=.052).

Table 4.13 describes the univariate logistic regression analyses for the dichotomous dependent variable, preterm labor. This table contains the relevant fatigue and occupational model at the top of the table but only the dichotomized fatigue variable and posture subscale of the occupational fatigue index actually entered the model. In consideration of the structure of the modified Environmental Demands model, posture and fatigue, the independent variables of primary interest, were entered in the model first to examine and remove any shared variance that these variables might have with the other predictors. Then the other significant univariate variables were reviewed in the multivariate model for statistical significance, biological relevance, and goodness-of-fit. Criteria were set for removal from the model if (1) p-value increased to over 0.15, (2) variable was seen as biologically irrelevant or redundant, or (3) variable in the model led to a poor goodness-of-fit. Goodness-of-fit was evaluated using the Hosmer-Lemeshow test. This test uses a percentile grouping referred to as the "deciles of risk." It describes how effective a model is in predicting an outcome variable. A significant (p < .05) is indicative of poor goodness-of-fit.

Taking these criteria in consideration for model building, anxiety was removed from the model for statistical reasons, education was removed as it was deemed to be highly redundant with officer rank (see Appendix E). Total weight gain taking in consideration gestation age, was removed from the model when the Hosmer-Lemeshow test was 14.5763, p=.0679 with it in the model and, without it, was calculated at 1.592, p=.9911.

The variables "work nights" and "low caffeine intake" were determined to be biologically relevant by virtue of a skewed confidence interval where the upper confidence limit of both was over 3.00. This suggests that the possible risk of having preterm labor among women working nights who also had low caffeine intake was as high as three times that of women not working nights who had high caffeine intake. The model, after removal of non-significant, biologically unimportant variables is found in Table 4.14.

Potential confounders (see Table 4.15) were tested with the seven main effects using multivariate logistic regression techniques. According to Hosmer-Lemeshow (1989), one determines the confounder status of a covariate by comparing the estimated coefficient for the risk factor, with and without the risk factor. A significant change in the coefficient, as well as change in the log likelihood, would indicate if the covariate is a confounder and should be included in the model regardless of statistical significance. For the preterm labor model, only hemoglobin was determined to be a confounder as evidenced by a significant coefficient change in "working nights" and a large log likelihood change of 5.57.

Table 4.16 contains examinations for interactions in the preterm labor model. Interactions of the main effects with fatigue as well as hemoglobin (identified confounder) were investigated. A variable is an "effect modifier" (interacts with main effects) only when the interaction term added to the model is both biologically meaningful and statistically significant. Only the fatigue-caffeine relationship was considered an interaction as evidenced by a significant change in the log likelihood and by this interaction attaining statistical significance.

The final multivariate logistic model for preterm labor (see Table 4.17) included three significant variables: low sleep disturbance, officer rank and negative life events. Officers with low sleep disturbance had 2.3 to 2.7 times the risk of having a preterm labor. The 95% confidence interval for negative life events was nearer to unity but still contributed significantly to the prediction of preterm labor. A graph of the interaction (see Figure 4.2) indicated that fatigue severity was not affected by women with high caffeine intake but at higher fatigue levels, the probability of the low caffeine intake group having preterm labor decreased, nearly matching the high caffeine group at the preterm labor probability of 0.1. Goodness-of-fit test for this model was 5.09 or p=.748 indicating a good fit.

Examination of the model for any observations that appear to exhibit an especially poor fit to the model was accomplished through Chi square change (studentized residual squared divided by 1 minus the leverage), deviance (standardized residual squared) and Cook's distance. Chi square change of more than 4.0 indicate values greater than 95% above the standard distribution of what could be predicted for this model. Twenty-six women were identified in this manner with Chi square change ranging from 36.2 to 4.2. Appendix F contains a detailed description of the two main outliers for this model and why they should be kept in the model. Appendix G contains graphs of Chi square change as part of the residual analysis for this model.

Logistic regression analysis indicated that the risk of preterm labor increased 1.8 times with perception of low fatigue severity and there was a biologically important, but

Table 4.13

Factors - Univariate Model (<u>p<.25</u>)				
Variable	β	SE	OR	95%CI	p-value
Fatigue Severity	009	.005	.99	(0.97,1.00)	.073
Fatigue (dichotomized)	.63	.33	1.8	(0.98,3.59)	.054
Energy	001	.015	.99	(0.96, 1.03)	.939
Occupational Fatigue	.14	.16	1.15	(0.84,1.56)	.364
Occupational Fatigue (dichotomized)	.35	.31	1.4	(0.76,2.65)	.26
Posture (subscale of Occupational Fatigue Index)	.48	.31	1.62	(.87, 3.01)	.12
Anxiety	06	.045	.94	(.86, 1.03)	.18
Sleep Disturbance (dichotomized)	.73	.32	22.08	(1.1, 3.9)	.023
Total Weight Gain/ Gestation	67	.44	.51	(.21, 1.22)	.13
Caffeine (dichotomized)	.61	.32	1.85	(.97, 3.5)	.059
Social Support (friend)	.02	.01	1.02	(.98, 1.05)	.23
Work Nights (dichotomized)	36	.31	.69	(.78, 2.64)	.23
Officer Rank (dichotomized)	1.05	.42	2.86	(1.23,6.64)	.01
School	114	.08	1.12	(.94, 1.32)	.19
Negative Life Events	.019	.014	1.01	(.99,1.03)	.18

<u>Preterm Labor By Fatigue, Energy, Occupational Fatigue and Significant Prognostic</u> Factors - Univariate Model (p < 25)

Table 4.14

<u>Multivariate Regression Model for Preterm Labor(n=359) After</u> Deleting Non-significant Variables (Controlling for Fatigue and Posture)

Step	Variable	β	SE	OR	95%CI	p-value	-2LL
1	Posture	45	.32	1.58	(0.84, 2.94)	.148	281.15
	Less Fatigue	.61	.33	1.84	(0.96, 3.52)	.064	
2	Sleep Disturbance	.92	.38	2.52	(1.18, 5.36)	.016	263.11
	Officer Rank	.97	.46	2.64	(1.06, 6.54)	.036	
	Negative Life Events	.043	.017	1.04	(1.01, 1.07)	.010	
	Work Nights	.48	.33	1.61	(0.84, 3.09)	.148	
	Low Caffeine Intake	.58	.34	1.78	(0.91, 3.51)	.091	
Hosm	er-Lemeshow Statistic = 1.592	2 df=8	8 p=.9	911			

Note: -2LL = Log Likelihood

Table 4.15 Multivariate Model for Preterm Labor Showing Evidence of Confounding

Model Ln(Preterm Labor = β_0 + β 1(Posture.) + β 2(Less Fatigue) + β 3(Sleep Disturbance) + β 4(Officer) + β 5 (Negative Life Events)+ β 6(Work Nights)+ β 7(Low Caffeine)+ β 8(Potential Confounder)

Potential Confounder	β1	β2	β3	β4	β5	β6	β7	β 8	LL	G
Main Effects	.32	.50	.92	.96	.04	.47	.58		263.111	
Ethnicity	.29	.51	.93	1.06 _.	.04	.48	.55	.40	261.44	1.67
Age	.30	.51	.95	1.12	.04	.48	.59	.02	262.793	0.32
Hours Work	.37	.49	.95	1.04	.04	.51	.59	02	262.203	0.91
Exercise	.32	.50	.92	.96	.04	.47	.58	.02	263.07	0.04
Smoking	.28	.52	.95	1.09	.04	.47	.63	.42	261.49	1.62
Hemoglobin (<10mg/dl)	.23	.53	.90	1.08	.04	.57	.66	11	257.54	5.57

Table 4.16 Multivariate Model for Preterm Labor Showing Evidence of Interaction

Model Ln(Preterm Labor) = $\beta_0 + \beta_1$ (Posture.) + β_2 (Low Fatigue) + β_3 (Sleep Disturbance) + β_4 (Officer) + β_5 (Negative Life Events) + β_6 (Work Nights)+ β_7 (Low Caffeine)+ β_8 *(other variables in model)

Interaction	LL	G	p-value
Main Effects only	255.72		
Fatigue*Posture	254.799	.924	.3448
Fatigue*Sleep Dist.	254.630	1.09	.2945
Fatigue*Officer	254.564	0.159	.6931
Fatigue*Neg. Life Events	255.564	0.374	.5420
Fatigue*Work Nights	254.776	0.947	.3329
Fatigue*Caffeine	255.658	4.06	.0479
Fatigue*hemoglobin	255.652	0.071	.7900
Hemoglobin*Posture	255.263	0.46	.4946
Hemoglobin*Sleep Disturbance	255.721	.002	.9600
Hemoglobin*Officer	255.597	0.126	.7251
Hemoglobin*Nights	255.004	0.719	.4002
Hemoglobin*caffeine	254.804	0.919	.7996



Severe Fatigue

Table	4.17 Final Multivariate Reg	ression N	lodel fo	or Preter	m Labor(n=359) Inclu	iding
Step	Variable	β	SE	OR	95%CI	p-valı	ie -2LL
1	Posture	.40	.32	1.49	(0.79, 2.80)	.21	277.56
	Less Fatigue	.58	.333	1.79	(0.93, 3.44)	.078	
2	Sleep Disturbance	.86	.39	2.36	(1.09, 5.07)	.028	251.65
	Officer Rank	1.01	.47	2.75	(1.08, 6.98)	.033	
	Negative Life Events	.048	.02	1.05	(1.01, 1.08)	.006	
	Work Nights	.59	.34	1.80	(.93, 3.53)	.082	
	Caffeine	22	.57	.79	(.26, 2.45)	.69	
	Low Hemoglobin	.99	.64	2.72	(.76, 9.59)	.12	
Hosm	Caffeine*Fatigue er-Lemeshow Statistic 5.0941	1.51 df = 8 p	.76 = .7475	4.54	(1.01, 20.35)	.048	

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statistically insignificant, relationship between posture (eg. long periods of standing, stretching, etc.) and preterm labor. Hence, for preterm labor, hypotheses 2.1 and 2.3 were not supported in this study. In the final multivariate model, both posture and low fatigue were still biologically important predictors of preterm labor but not statistically significant.

Predictors of Preterm Birth

For preterm birth, bivariate analyses were also done to determine candidates for the multivariate model. As described in Appendix AA, the following internal environmental demands were selected: sleep disturbance (t= -2.011, p=.045), age (t=1.8118, p=.07). and hemoglobin (t=1.520, p=.13). Among the external environmental demands (see Appendix BB), housing condition, number of people in household (χ^2 =1.786, p=.181), children less than 3 years old (χ^2 =1..520, p=.218), less positive life events (t=11.981, p=.2.21), education (t=1.9181, p=.048) income (t=1.255, p=21) and officer rank (χ^2 =10.56, p=.001) were included. None of the fatigue severity or occupational fatigue variables (see Table 4.12) met criteria for the model with preterm birth as the dependent variable.

Table 4.18 contains the univariate logistic regression analyses for the dichotomous dependent variable, preterm birth. None of the fatigue, energy, or occupational fatigue variables actually entered the multivariate model. They are being shown to re-emphasize their lack of statistical significance in this study. The covariate, children less than 3 years old was not advanced to the multivariate model because when placed in univariate logistic regression, it lost its statistical significance (p>.25). With

this model, all variables except negative life events, were dichotomized due to ease in interpretation before variable reduction. Then, similar to the criteria listed for preterm labor, other significant univariate variables were reviewed in a multivariate model for statistical significance, biological relevance and goodness-of-fit. Criteria were set for removal from the model if (1) p-value increased to over 0.25, (2) variable was seen as biologically irrelevant or redundant or (3) variable in the model led to a poor goodness-of-fit. The standard was lowered from the preterm labor model as there appeared to be less statistical power in this model due to only 34 preterm birth respondents as opposed to 50 women who were diagnosed with preterm labor.

Taking these criteria into consideration in model building, age, positive life events and hemoglobin were removed from the model for statistical reasons. Education and income were removed due to redundancy with officer rank (see Appendix E). Covariates of marital status and people in the household, although less statistically significant, were deemed an important variable due to skewed confidence interval where the upper limit was over 3.00, suggesting a possible risk of having preterm birth of over three times higher by married women (n=219) with fewer people in the household than single women (n=140) with a more crowded household.

Potential confounders (see Table 4.19) were tested with the four main effects using multivariate logistic regression techniques. For the preterm birth model, negative life events was determined significant as evidenced by a significant coefficient change in sleep disturbance and a large log likelihood change of 4.59.

Table 4.20 contains examinations for interactions in the preterm birth model. These were done with the identified confounder, negative life events, as it was suspected that the large change in log likelihood was also because this covariate may be interacting with other variables, especially those with large coefficient changes. This turned out to be the case as negative life events did show evidence of interaction with sleep disturbance.

The final multivariate logistic model for preterm birth (see Table 4.21) included only one significant variable, officer rank and one interaction. Officers had four times the risk of having preterm birth. A graph of the interaction (see Figure 4.3) indicated that high sleep disturbance had little effect on the probability of preterm birth with increase in negative life events. However, women with low sleep disturbance and high negative life events had an increased probability of preterm birth. The interaction with women with the high sleep disturbance occurred when the incidence of life events was low. Goodness-of-fit with the model was calculated at 12.227, p=.1414

Chi square change and other logistic regression residual analysis calculations were done with this model. Twenty four women were identified to be "outliers" with Chi square change ranging from 39.02 to 4.75. Appendix F, again, contains a detailed description of the two main outliers for this preterm birth model and why these cases need to be kept in the model.

This review of predictors of preterm birth indicated that there was no relationship between shortened duration of pregnancy and fatigue perception or occupational fatigue. Hence, in relationship to preterm birth, hypotheses 2.2 and 2.4 were not supported in this study.

Table 4.18

Preterm Birth By Fatigue, Energy, Occupational Fatigue and Significant Prognostic Factors (p<.25)

Variable	β	SE	OR	95%CI	p-value
Fatigue Severity	004	.006	.99	(0.98,1.01)	.4943
Energy	002	.019	.99	(0.96,1.03)	.8879
Occupational Fatigue	062	.19	.93	(0.64,1.32)	.7489
Sleep Disturbance	02	.01	0.97	(0.95, 0.99)	.046
Age	.06	.03	1.06	(0.99,1.13)	.07
Marital Status	.63	.40	1.9	(0.84,4.1)	.12
Officer Rank	1.39	.46	4.0	(1.6,9.9)	.002
Income	.07	.06	1.07	(0.96,1.21)	.21
Positive Life Events	03	.02	0.97	(0.94,1.01)	.22
Hemoglobin .	.26	.17	1.29	(0.93,1.79)	.13
Education	.18	.09	1.19	(0.99,1.43)	.052
People in Household	.58	.44	1.78	(.75,4.24)	.19

Table 4.19 Multivariate Model for Preterm Birth Showing Evidence of Confounding

Model Ln(Preterm Birth) = $\beta_0 + \beta_1$ (Sleep Disturb.) + β_2 (Rank) + β_3 (Marital) + β_4 (People in House) + β_5 (Potential confounder)

Potential Confounder	β1	β2	β3	β4	β5	LL	G
Main Effects	.62	1.23	.45	.66		210.992	
Ethnicity	.62	1.23	.45	.65	01	210.834	.158.
Age	.60	1.08	.43	.72	.02	210.767	.225
Hours Work	.63	1.28	.47	.66	01	210.752	.240
Neg. LEQ	.82	1.28	.56	.60	.03	206.404	4.588
Exercise	.62	1.125	.46	.67	07	210.718	.274
Smoking	.62	1.23	.46	.66	.01	210.991	.001
Social Support	.65	1.24	.49	.68	005	210.690	.302

Table 4.20 Multivariate Model for Preterm Birth Showing Evidence of Interaction

Model Ln(Preterm Birth) = $\beta_0 + \beta_1$ (Sleep Disturb.) + β_2 (Rank) + β_3 (Marital) + β_4 (People in Home) + β_5 (Negative Life Events) + β_5 *(other variables in model)

Interaction	LL	G	p-value
Main Effects only	206.404		
Neg LEQ*Sleep Disturbance	200.985	5.42	.0278
Neg LEQ*rank	206.221	0.183	.6682
Neg LEQ*Marital	206.396	0.008	.9297
Neg LEQ*People in House	204.270	2.13	.2183

Table 4.21

Final Logistic Multivariate Regression Model for Preterm Birth (n=359)

Variable	β	SE	OR	95%CI	p-value
Sleep Disturbance (SD)	38	.65	.68	(0.18, 2.46)	.56
Marital Status	.52	.43	1.69	(0.71, 3.98)	.23
Officer Rank	1.42	.50	414	(1.54, 11.08)	.005
People in Household	.61	.455	1.85	(0.75, 4.14)	.17
Negative Life Events (NLEQ)	02	.04	.97	(.91, 1.04)	.52
NLEQ * SD	.09	.04	1.1	(1.01, 1.2)	.027

Hosmer-Lemeshow statistic = 12.227, df=8, p=1414

Figure 4.3 Preterm Birth Model Interaction



Negative Life Events

Preterm Labor and Birth, Fatigue, and Hours of Work

This section addresses hypotheses 3.1 to 3.4 which have to do with repeated measures of fatigue and hours worked for women in the study who were diagnosed with preterm labor or delivered prematurely. Ludbrook ((1994) describes repeated measures ANOVA as measuring three hypotheses: (1) treatment effect (level of variable classfied by treatment averaged over time differs by group), (2) time (level of variable differs over time) and (3) interaction between time and treatment (level of variable differs over time according to treatments). In this study, we are most interested in the interaction between time versus condition of the subject depending on what the treatment is—whether it is fatigue or number of hours worked. For repeated measures of fatigue, the respondents in this study were given fatigue diaries to fill out at six designated times over two consecutive work days (morning, noon, evening). Table 4.22 shows the two-way repeated measures analysis of variance (ANOVA) for preterm labor in relation to fatigue levels. Although there is a difference between subjects over time in fatigue (F=51.57, p=.001), there is no difference in the interaction of fatigue and preterm birth over time (F=.998, p=.417).

Similarly, Table 4.23 shows the repeated measures ANOVA for preterm birth in relation to fatigue levels. Again, change in fatigue over time is significant (F=39.069, p=.001) but not the interaction, fatigue by preterm birth (F=.641, p=.668). On the other hand, with hours of work (see Table 4.24, there is a difference between preterm birth and hours worked (F=34.389, p<.001) and preterm labor and hours worked (F=34.818, p=<.001) in Table 4.25, the implications of which will be discussed in Chapter 5.

The condition of compound symmetry—that is, the correlation between any pair of observations on a given subject and the correlation on pairs of observations between subjects is zero—is an assumption that needs to be tested. When compound symmetry does not exist, the F values do not follow the theoretical F distribution and results will be biased toward rejecting the null hypothesis (smaller F values than data can justify). In practice, behavioral data rarely meet the assumption of compound symmetry (Munro, 1993). Mauchly's test of sphericity is used to test the assumption of compound symmetry. If this test is significant, the assumption has not been met and the univariate approach (i.e.no adjustment N degrees of freedom when interpreting the F-value) is not appropriate. As can be seen in Table 4.22. Mauchly's test of sphericity is significant. Adjustments can be made to the degrees of freedom (df) to decrease the likelihood of Type I error via the "episilon" correction. Epsilon is multiplied by the df in the numerator and denominator and this new df is used to test F. Huynh-Feldt is less conservative than the Greenhouse-Geisser definition of "epsilon" but is considered more "robust." (Glanz & Slinker, 1990). For preterm labor and preterm birth, fatigue over time and hours of work over 5 month are still significant when df are corrected by the Huynh-Feldt epsilon factor (see Tables 4.22 to 4.25).

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Table 4.22 Repeated Measures Analysis of Variance for Pearson-Byars Feeling

Tone Diary for 6 Fatigue Measures Over Two Consecutive Work Days for Preterm Labor (n = 339)

Mauchly's Test of Sphericity = .506, p = .001 Huynh-Feldt = .811

		Be	tween Subjects	Effects					
Source	Sum of Squares	df Squa	Mean re	F	p-value				
Constant	25711.29	1	25711.29	1624.286	.001				
Preterm Labor	2.516	1	2.516	.159	.690				
		W	ithin Subjects	Effects					
Source	Sum of Squares	df Squa	Mean re	F	p-value				
Fatigue	919.682	5	183.936	51.57	.001				
Fatigue* Preterm Labor	17.806	5	3.561	.998	.417				

Huynh-Feldt x df correction \rightarrow df of 4.055 and 1366; F of 51.57 is still significant (p<.001, 4.32, when df - 4, ∞)

		Within S	ubjects Contr	asts for Fatigue	e
Source	Sum of Squares	df Squa	Mean re	F	p-value
Linear (Fatigue)	99.648	1	99.648	24.353	.001

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Table 4.23 Repeated Measures Analysis of Variance for Pearson-Byars FeelingTone Diary for 6 Fatigue Measures Over Two Consecutive Work Days forPreterm Birth (n = 339)

Mauchly's Test of Sphericity = .507, p = .001 Huynh-Feldt = .811

	Between Subjects Effects							
Source	Sum of Squares	df Mean Square		F	p-value			
Constant	19219.35	1 19219.35		1213.683	.001			
Preterm Birth .401		1.401		.025	.874			
		Within Subjects Effects						
Source	Sum of Squares	df Mean Square		F	p-value			
Fatigue	697.481	5	139.496	39.069	.001			
Fatigue* Preterm Birth	11.448 N	5	2.290	.641	.668			
Within cells	6016.344	1685	3.571					

Huynh-Feldt x df correction \rightarrow df of 4.055 and 1366; F of 39.069 is still significant (p<.001, 3.32, when df - 4, ∞)

		;			
Source	Sum of Squares	df Squar	Mean e	F	p-value
Linear (Preterm birth)	70.325	1	70.3255	17.130	.001

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Table 4.24 Repeated Measures Analysis of Variance for 5 Work Hours Measures OverOne to Five Months for Preterm Labor (n = 339)Mauchly's Test of Sphericity = .329, p <.001</td>Huynh-Feldt = .695

	Between Subjects Effects							
Source	Sum of Squares	df Square	Mean e	F	p-value			
Constant	832818.0	1	832818.0	3445.141	<.001			
Preterm Labor	15901.88	1 15901.88		65.782	<.001			
	Within Subjects Effects							
Source	Sum of Squares	df Mean Square		F	p-value			
Hours Wk	63300.79	4	15825.2	199.381	<.001			
Hours Wk* Preterm Labo	11054.21 or	4	2763.552	34.818	<.001			
Within cells	105405.4	1328	79.372					

_Huynh-Feldt x df correction \rightarrow df of 2.78, 922.96 ; F of 199.381 and 34.818 are still significant (p<.001, 2.60, when df - 3, ∞)

		;			
Source	Sum of Squares	df Squa	Mean re	F	p-value
Linear (Hrwork)	60237.54	1	60237.54	409.052	<.001
Linear (Hrwork* Preterm Labor)	10430.90	1	10430.90	70.833	<.001

Table 4.25 <u>Repeated Measures Analysis of Variance for Pearson-Byars Feeling Tone</u> <u>Diary for 5 Work Hours Measures Over One to Five Months for Preterm Birth (n = 339)</u>

Mauchly's Test of Sphericity = .338, p = .001 Huynh-Feldt = .706

	Between Subjects Effects							
Source	Sum of Squares	df Mean Square		F	p-value			
Constant	59227.2	1	492278.2	2301.694	<.001			
Preterm Birth	10727.4	1	10727.4	41.688	<.001			
		Wi	thin Subjects	Effects				
Source	Sum of Squares	df Squar	Mean e	F	p-value			
Hours Wk	55614.75	4	13903.69	174.967	<.001			
Hours Wk* Preterm birth	10930.85	4	2732.712	34.389	<.001			
Within cells	105528.8	1328	79.464					

_Huynh-Feldt x df correction \rightarrow df of 2,824, 937.586; F of 174.967 and 34.389 are still significant (p<.001, 2.60, when df - 3, ∞)

	Within Subjects Contrasts for Fatigue						
Source	Sum of Squares	df Square	Mean	F	p-value		
Linear (Hrwork)	51266.32	1	51266.32	343.905	<.001		
Linear (Hrwork*Preterr	9 8 30.102 n Birth)	1	9830.102	65.942	<.001		

	Term	<u>1 Labor</u>		Preter	<u>m Lat</u>	<u>oor</u>		
Variable	Mea	n (SD) S Range	Sample	Mean	(SD)	Sample Range	Instrument. Range	T- Test
Morning (Day 1 & 2)	4.5	(2.11)	0-10	4.4 (2.48)	0-10	0-10	.324 (p=.746)
Midday (Day 1 & 2)	4.4	(1.99)	0-10	4.3 (2.05)	0-10	0-10	.404 (p=.686)
Evening (Day 1 & 2)	6.4	(2.17)	0-10	6.4 (2.06)	0-10	0-10	.059 (p=.953)
Evening- Morning Difference	1.97	(2.53)	0-10	1.98 ((2.68)	0-10	0-10	025 (p=.980)
Variable	<u>Term</u> Mea	n Birth n (SD) S Range	ample	<u>Preter</u> Mean	<u>m Bir</u> (SD)	<u>th</u> Sample Range	Instrument. Range	T- Test
Morning	4.5	(2.13)	0-10	4.6 (2	2.44)	0-10	0-10	196 (p=.845)
Midday	4.4	(1.96)	0-10	4.2 (2	2.37)	0-10	0-10	.615 (p=.539)
Evening	6.4	(2.17)	0-10	6.5 (1	.98)	0-10	0-10	130 (p=.897)
Evening- Morning Difference	1.97	(2.55)	0-10	1.94 (2.52)	0-10	0-10	.072 (p=.943)

Table 4.26 Average Pearson-Byars Fatigue Scores and Preterm Labor and Delivery

In a separate but related analysis, differences between first and second day morning, midday and evening measurements of the Pearson-Byars were compared. Morning fatigue scores (r=.578, p<.001), midday scores (r=.621, p<.001) and evening scores (r=.606, p<.001) were highly correlated. Two consecutive workday averages of



the morning, midday and evening scores and the difference between evening and morning fatigue scores were calculated. This was followed by t-test analyses with dependent variables, preterm labor and preterm birth for the three time periods and the difference between evening and morning fatigue. No significant differences were found between average fatigue at the three time periods, the difference between evening and morning fatigue and preterm labor and delivery (see Table 4.26).

Hypotheses 3.1 and 3.2 were not supported similar to results with other fatigue measuring tools. Hypotheses 3.3 and 3.4, however, were supported. As women were diagnosed with preterm labor and placed on bedrest or delivered early, their weekly hours of work decreased over time.

Summary of Major Findings

The instruments used to measure independent variables in this study were internally consistent, with Cronbach alpha coefficients between .76 and .97. The instrument used to measure fatigue, Visual Analog Scale, had concurrent validity scores with subscales of the POMS and Pearson's Byars Feeling Tone Scale. A factor analysis did confirm the construct validity of the VAS-Fatigue as appropriate for measuring fatigue and energy, explaining 66.23% of the variance.

The sample consisted of 359 women, predominantly white (61%), enlisted (91%), Navy (72%) with a mean age of 23.9 years. Average education was 12.9 years and most (64%)worked at military occupation specialty category 1 (moderate stress) position. Forty-two percent of the pregnant women experienced severe fatigue as defined by the VAS-F. Fifty active duty women were diagnosed with preterm labor of whom 34 women went on to deliver prematurely.

Hierarchical and stepwise linear regression model with 11 variables explained 36% of the variance in perceived fatigue severity.' Fourteen variables explained 30 % of the variance in perceived energy. Independent variables making significant unique contributions to the perception of fatigue severity were sleep disturbance, depression, negative life events, and role demands. For energy, independent variables making unique contributions were role demands, sleep disturbance, negative life events, age, marital status and strenuous exercise.

Hierarchical logistic regression models examined fatigue and other univariately significant covariates as predictors of preterm birth or labor. With the 34 women who delivered prior to 37 weeks, only the officer rank emerged as the statistically significant factor in predicting preterm birth. With the 50 women who were diagnosed with preterm labor, the posture subscale of the occupational fatigue index and perception of low fatigue severity were significantly associated with their diagnosis. These variables, when placed in a multivariate model, were no longer significant.

Repeated measures analyses of variance were performed and averages of morning, midday and evening fatigue were compared to determine the diurnal change in association with preterm birth and preterm labor. A change in fatigue was not associated with preterm birth or labor but there was a significant relationship between decreased work hours, increased preterm labor and preterm birth.

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CHAPTER FIVE

DISCUSSION

Introduction

Chapter Five includes four sections. First, the findings of this study are interpreted in relation to the hypotheses and the significance of the results presented. Second, the strengths and limitations of the study are examined. Next, implications for nursing are reviewed. Lastly, future directions for research are proposed.

Interpretation and Significance of Results

Results Compared to Military Studies

The sample consisted of 359 active duty women, 67% who were primigravidas, 61.8% of whom were White, 25% African-American, 8% Latino and 2.2% Asian/Pacific Islander which reflects the ethnic demographic composition of women in the United States armed forces (Institute of Medicine, 1995). Ninety-one percent of the sample was enlisted compared to an actual population percentage of 85% belonging to the enlisted ranks. The age distribution of this sample also reflected the relatively skewed distribution of women in the military with more than half of the population under the age of 26. Education (65% high school only), marital status (61% were married), alcohol intake (96% denied drinking), maternal weight gain (19% gained <25 pounds; 48% gained >35 pounds) and prepregnancy body mass index (12% were classified in "thin" or <19.8 category) were comparable to other large studies of military active duty pregnant women (Adams et al., 1993; Magann et al., 1995).

There were also differences in demographic variables from other studies. In this study, 10% indicated that they were smoking at 22-26 weeks GA, not including 29% who

admitted to having quit which could have been interpreted as "before pregnancy." This 10% may be an underestimation since data were acquired by self-report. The 39% may be an over-estimation due to possible misinterpretation of what "I quit" meant. The 10% estimation is comparable to recent Navy studies (Spandorfer & Graham, 1996; Magann et al., 1995) but is considerably less than the 25-28% tobacco exposure that was found in Army (Adams et al., 1995) and Air Force (Hauth et al., 1983) and a 1984 government report.

Magann and associates (1995) obtained a more even distribution of job titles in a Navy and Marine Corps sample as defined by military occupational specialty with just 28% in moderate stress, administrative jobs as compared to 64% in this study and 31% in hazardous duty (exposure to chemicals) compared to just 8.6% in the present study. This may have been due to changes in policy (see Appendix I) where exposure to specific chemicals or ionizing radiation is specifically prohibited. In the only other military study (Messersmith-Heroman, 1994) where income was reported, 56% listed annual incomes of less than \$20,000 per year while, in this study, only 45% had incomes less than \$20,000. This was because the Messersmith-Heroman study was limited to only enlisted deliveries while this study examined both enlisted women and officers. Messersmith-Heroman and associates also used the same social support behaviors index in their study of 100 military women and found similar moderately high (101.85 \pm 26.11) scores compared to the present study (103.7 \pm 20.1).

Finally, anemia (hemoglobin <10.0mg/dl) occurred at a slightly higher frequency (7.5%) than in two previous studies (4-5%) of military women (Fox et al., 1977; Kruger,

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1979). In contrast, Spandorfer and Graham (1996) found 44% of a group of 'seagoing' pregnant Navy women to be anemic and Adams and associates (1995) found 19.7% of enlisted Army women to have anemia. Unfortunately, there were no definitions of anemia provided for that studies. A recent study of non-pregnant military women (King et al., 1993) showed a declining adequacy of nutritional intake, especially calcium and iron. Hemoglobin of West Point female cadets in 1980 was 13.3 mg/dl \pm 1.2 while in 1990, it had declined to 12.5 mg/dl \pm 1.0. While these values may be within normal limits, the military nutritionist authors expressed concern. Pregnant military women, because they are required to meet military body weight standards within 6 months after childbirth, may further limit their food intake during pregnant, possibly placing the pregnancy in jeopardy secondary to iron deficiency anemia (Scholl et al., 1993).

<u>Results Compared to Civilian Studies</u>

Other variables in this study can be compared to civilian studies of pregnant women. Depression as measured by a subscale of the POMS averaged 4.16 ± 4.03 or about the same as a Time 3 (22 weeks gestation) measurement of depression [mean of 4.12 - chorionic villus sampling (CVS) and 3.73 - amniocentesis] for women undergoing prenatal diagnosis (Tunis et al. 1990). Anxiety levels were slightly lower (eg. 5.13 opposed to 6.99 for the CVS group). Similar to the women in the prenatal diagnosis study, military women in this study had relatively low mood disturbance. This was a prospective study of women with no history of negative pregnancy outcome, most were married, physically healthy and assured of medical care during their pregnancy. The average sleep disturbance score was 48.9 ± 15.78 , very similar to the average day shift score in a shift work study (Lee, 1992) of non-pregnant nurses (47.3 ± 13.8) but lower than a study (Lee & DeJoseph, 1992) of pregnant nurses (62.8 ± 24.9). Waking up during sleep had the same prevalence for all three studies. But the active duty women, similar to the non-pregnant employed women, did not have as much difficulty falling asleep as the pregnant civilian nurses. This is surprising since difficulty falling asleep is a function of sleep deprivation and one would anticipate that the military woman who is technically "on-call" 24 hours may be more at risk for sleep disturbances.

Caffeine intake was similar to two other recent studies (Pastore & Savitz, 1995; Fortier et al., 1993) but far less than pregnant women in two European studies (Peacock et al., 1995; Larroque et al., 1993) where fewer abstained from caffeine. Twenty-three percent of the military women denied drinking beverages with caffeine while 7.6% had moderate to heavy intake (more than 150 mg per day). There may have been some underreporting of use because of discussion at obstetrical orientation classes of the possible harmful effects of caffeine especially in combination of lifestyle choices such tobacco and alcohol intake (Hinds et al., 1996).

Activity level/exercise has been measured in hours per day (Klebanoff et al., 1990), kilocalorie output (Magann et al., 1996), as part of an index of different activities (Hickey et al., 1995) or as a dichotomous variable (Berkowitz et al., 1983). This makes it difficult to compare studies. Nevertheless, in contrast to a study of pregnant civilians where 66% denied participating in leisure activity (Berkowitz et al., 1983), only 28% of the military women denied exercising at all during pregnancy (marked 'zero' for both

moderate and strenuous exercise). Henriksen and associates (1995) found 7% of Danish employed women did "moderate to heavy activity" greater than 3 hours a week which approximated the 2.2% of military women who did "moderate" exercise and the 10% who did "strenuous" exercise in this study. As with the weight standards noted above, all service members must pass cardiorespiratory endurance fitness standards within 6 months after delivery or face discharge from the military (Institute of Medicine, 1995). This increases the motivation to exercise during pregnancy.

Housing conditions showed that active duty women lived in civilian apartments assisted by the recent Secretary of the Navy authorization (see Appendix I) for basic allowance for quarters (BAQ) for off-base housing. Role demands assessment indicated that most non-occupational time was spent in homework type activities, leisure time activities and maintaining adult relationships. It was difficult to find similar measures in the literature. Berkowitz and associates (1983) reported 23% of the pregnant women in their study worked <10 hours per week doing household chores compared to 71% who reported working <10 hours per week at household tasks among military women. However, only about half of the women in the Berkowitz study worked while in the present study, 100% of the military women worked. More military women did not have children living in the household (70.7%) compared to 23.3% in civilian studies (Reeves et al., 1991) which is similar to other military studies (Magann & Nolan, 1991).

Occupational fatigue was measured by the Occupational Fatigue Index (OFI) where mental stress (repetitive work), posture (standing for long periods)and environmental exposure (environmental stress from cold, heat, moisture and chemicals) were the most commonly chosen sources of job fatigue. Work on industrial machines

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(15% versus 1.1%) and physical exertion (30% versus 7.8%) were far more common in the original study done retrospectively by Mamelle and associates (1984) on 1928 working women in France. In another retrospective study, Luke and colleague (1995) found much higher exposures to sources of fatigue in a nation-wide study of nurses: posture (90% versus 31%), physical exertion (50% versus 7.8%), mental stress (72% versus 55.4%) and environmental exposure (45% versus 21.7%). In a prospective study in Alabama of 1177 high risk, low income women (Hickey et al., 1995), there was a large disparity between the five fatigue sources and the present study, with much larger number of exposures reported by the low income women. Only in a Danish study of 8711 women (Henriksen et al., 1995) was there no great difference in one source related to posture. Twenty-nine percent of the Danish women reported that they stood >2-5 hours in their jobs in the second trimester as opposed to 31% of the military women. Selective recall bias by the women in the first two studies may have been influenced by pregnancy outcome. In the study of the low income women, at the time the questionnaire was completed at 24 to 26 weeks GA, 50.3% of the African American women and 64.6% of the White women had already stopped working; hence, the sampling strategy might have biased their self-report regarding work conditions. On the other hand, 74% of the women in the Danish study were still working at 30 weeks gestation compared to 97.4% who were still working in the military sample. Hence, the exposures found in the earlier studies may have been exaggerated or military policy (Appendix I) might have protected the active duty women from extremes in exertion.

Other measured elements of occupational conditions include hours worked per week, weekend/shift work and satisfaction with work. While 4% of the low income

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women in the Alabama study (Hickey et al., 1995) worked longer than 40 hours per week and 4% of the nurses in the Luke study (1995) worked longer than 36 hours, 47% of the military women at 22-26 weeks GA worked longer than 40 hours and 21% worked longer than 45 hours. Fifty-seven percent of women enrolled in the 1980 National Natality Study (Peoples-Sheps et al., 1991) worked longer than 40 hours per week but it was not clear when in the pregnancy this was being measured. A previous study on active duty women showed the average hours per week to be 39.18 ± 6.99 (Messersmith-Heroman et al., 1994) compared to 42.66 ± 6.88 in this study. No other studies on shift work/night hours and satisfaction with work (which is different from not being motivated to continue working as found in Homer et al. 1990 study) could be found in the literature for comparison.

The average scores for positive life events (14.29 ± 10.28) and negative life events (10.78 ± 9.6) were similar to life event scores in a study of non-pregnant women (Lee et al., 1994). Similar to research on European pregnant women (Newton et al., 1979; Hedegaard et al, 1996), financial changes and alterations in relationship with spouse/partner were considered major life changes. However, sleep, eating and work condition changes were more of a concern for military women than physical illness in the Danish and British samples.

Fatigue Outcomes

Fatigue level as operationalized by VAS-Fatigue (44.28 ± 21.3) were higher than second trimester VAS-F findings (38.8 ± 24.3) of a longitudinal study (Pugh & Milligan , 1995) of low income multiparous women but lower than the third trimester VAS-F findings of middle class income primiparous (64.16 \pm 17.92) and multiparous (64.79 \pm 19.27) women (Waters & Lee, 1996). The differences in fatigue could largely be explained by the trimester difference as third trimester fatigue is generally higher than the second (Lee & DeJoseph, 1992; Reeves et al., 1991; Pugh & Milligan, 1995) and because fatigue was assessed during day-time clinic visits. The Waters and Lee study reflected evening fatigue scores. VAS-F findings in 24 employed pregnant nurses (Lee & DeJoseph, 1992) indicated similar fatigue levels (64.7 ± 27.3) to the higher income; unfortunately, the effect of trimester energy level was diluted as the sample was divided, 8 respondents per trimester. On the other hand, POMS fatigue scores (9.55 ± 4.75) were higher than mean second trimester fatigue levels of high income older women undergoing chorionic villus sampling (8.83) or amniocentesis testing (8.43). The military women, however, indicated only half the vigor (6.71 ± 3.68) that the CVS sampling group reported (15.62). Van Lier and associates (1993) administered the Pearson-Byars Feeling Tone scale to first trimester women over 6 time periods in a single day and found the total score to be 37.6. In this study, the Pearson-Byars was summed per each measurement time. However, if the fatigue levels were totaled similar to the Van Lier study, the average fatigue diary score would have been 30.81 ± 9.7 . Fatigue may have been lower for the military women because they were in their second trimester, where energy levels are usually higher than in the first trimester (Lee & DeJoseph, 1992). Overall, it would appear that the women in this sample, were experiencing relatively higher fatigue and lower energy compared to other pregnant women at the same period of gestation.

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Correlates of Perceived Fatigue

Perceived fatigue was related to depression, anxiety, sleep disturbance and negative life events which was similar to findings in a study on non-pregnant women (Lee et al., 1994). Three interesting correlates included high caffeine intake, lower role demands and satisfaction with work/working weekends and fatigue. Caffeine's pharmacologic properties include central nervous system stimulation (Hinds et al., 1996) and possibly active duty women were using more caffeine to deal with their fatigue on the job or at home. Similarly, it appeared that the women dealt with their fatigue by taking on fewer demands at home. But, in contrast, if they were satisfied with their work, they may work harder, work weekends, and, consequently, be more fatigued. Fatigue was negatively related to hemoglobin, an indicator of poor dietary patterns (King et al., 1993) and low social support, which could be related to the negative attitudes still lingering in the military toward pregnancy or being relocated from friends and family frequently (Holm, 1992).

When fatigue and energy are conceptualized along the same continuum, internal demands (depression, anxiety, sleep disturbance and hemoglobin) and external demands (negative life events, social support and role demands) satisfied the definition as they were positively correlated with fatigue and negatively correlated with energy. Similar to a study of first trimester women (Reeves et al., 1991), younger women were more fatigued. External environmental demand variables associated with energy for this sample included: higher income, years of education, being married, and presence of children less than 5 years of age. The relationship of strenuous exercise to perception of energy will be discussed in the regression analysis section.

Fatigue Linear Regression Interpretation and Hypothesis Testing

In testing Hypothesis #1, hierarchical and stepwise multiple linear regression analyses were used to determine how much variance in the fatigue-energy continuum could be explained by internal and external environmental demands. Significant factors included 1) role demands, 2) negative life events 3) strenuous exercise, 4) age, 5) depression and 6) sleep disturbance. Thirty-six percent of the variance in the fatigueenergy continuum could be explained by these variables in hierarchical regression. In stepwise regression analyses, sleep disturbance and depression accounted for 34.5% of the variance in fatigue severity. Five variables (higher role demands, older age, more strenuous exercise, lower negative life events and lower sleep disturbance) accounted for 27.5% of the variance in energy level.

Even for military women, much of their role demand work is not done in the labor force. Much time was spent in roles such as homemaking, parenting and maintaining an adult relationship. These activities, often termed "invisible" as they are not recognized or given monetary compensation, are what women do to organize and integrate the household. DeJoseph (1993) has observed that these activities require "energy expenditure" and the compounding of a number of roles is stressful. Role specific strains having to do with the household role have been known to be stressful enough to be associated with negative birth outcomes (Pritchard & Mfphm, 1993). By the second trimester, this sample of military women may have already compensated for the increased energy for outside roles required by decreasing the number of non-occupational roles.

Another external demand, negative life events, explained a significant amount of variance in fatigue when internal demands were not entered in the model first. This is
because this variable moderately correlated (r= .41 to .54) with a number of the internal environmental demands (see Table 4.20) which could have confounded the effect negative life events had with fatigue. Rather than a simple count of life changes, life events perceived as stressful, like role demands, can be energy depleting (Hedegaard et al., 1996). As noted earlier, this study confirmed an earlier secondary analysis of data where fatigue in non-pregnant women was specifically associated with negative, as opposed to positive, events or a simple count of events (Lee et al., 1994).

Activity level, as expected, was positively related to the energy end of the continuum of fatigue. Engaging in strenuous exercise such as brisk walking (which could occur on the job) was associated with less fatigue. In the first National Health and Nutrition Examination Survey (NHANES), fatigue was negatively associated with physical activity. Respondents who were inactive had twice the risk of being fatigued compared those who were active (Chen, 1986). This sample of healthy active duty military women, motivated by the requirement of non-pregnant weight requirements by 6 months postpartum, were more active and, consequently, experienced less fatigue.

Like negative life events, age in this sample was highly correlated (r=.33 to .59) with other role demands, income and level of education which are all related to increased energy. In a qualitative study of older primigravidas (over age 35), Winslow (1987) reported that the older women felt an overall sense of well-being but found it tiring to maintain their full personal and professional schedules. But, due to increased maturity and success in solving problems in the past, they were able to overcome fatigue associated with home and work responsibilities. This may account for the increased energy with age in pregnant women and associated factors.

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Depression was an internal environmental demand that contributed much variance to fatigue even when external environmental demands were controlled. In NHANES, Chen (1986) reported that adults who suffer from depression are more likely to feel fatigued than those free of psychological problems. Pugh and Milligan (1995) also found depressive symptoms in low income multiparous women to be correlated with fatigue in all three trimesters. The investigators proposed a cyclic model to explain this phenomenon where anxiety (which had some association with depression in this study) fosters depression, which then enhances anxiety, which then increases fatigue. It would appear that as fatigue increases, it may become difficult to distinguish from depression with a one time measure. For example, depression, for this study, was only measured with five POMS items: sad, unworthy, discouraged, lonely, and gloomy. Fatigue was measured with the POMS adjectives; worn, fatigue, exhaust, sluggish and weary. Both sets of items imply slowing down and lack of energy. With more items, perhaps the sense of unhappiness and isolation that distinguishes depression from fatigue could be elicited.

The strongest predictor of fatigue and energy in this study was sleep disturbance, especially midsleep awakenings. This has been found in other samples of pregnant women (Lee & DeJoseph, 1992; Reeve et al., 1991; Lee et al. 1994; Waters & Lee, 1996) except for a recent study where sleep disturbance was narrowly defined as shorter periods of uninterrupted sleep (Elek et al., 1997). As noted earlier, since active duty women could be called to work at any time, sleep problems could be a crucial factor in contributing to fatigue. Military policy (see Appendix I) does not protect the women from disturbances in sleep.



Occupational fatigue and other related variables such as weekend work and satisfaction with work did not have a statistically significant unique contribution to the fatigue linear regression analyses. Studies that suggest that employment factors in pregnancy (Luke et al., 1995; Hickey et al., 1995) related directly to fatigue have been largely retrospective involving women accounting for their pregnancy outcomes. An alternative explanation could be that with increased activity at work, there would be a need for increased energy and the pregnant active duty woman would find means to accommodate for this.

Pregnancy Outcomes

Two pregnancy outcomes were examined in this study: preterm labor and preterm birth. They are related in that preterm labor is the start of cervical change and could be stopped by effective tocolysis either pharmacologically, by bedrest or by factors yet unknown. In contrast, preterm birth occurs as a result of failure of tocolysis or deliberate induction of labor due to maternal illness (only occurred with 1 of the preterm births) with subsequent delivery of the infant before 37 weeks GA. All of the 34 (9.5% of all births) women who had a preterm birth also had preterm labor but not all of the 50 (13.6% of all births) women who experienced preterm labor delivered early. The vast majority (79.4%) of those who had preterm births delivered after 35 weeks and only 2 women (5.8%) delivered before 30 weeks which is indicative of the relative healthiness of this sample after rigid exclusion criteria. Eighty-two percent of the preterm labor patients were diagnosed before 28 weeks and tocolyzed with bedrest which demonstrates the close monitoring exhibited in this sample by the medical system.



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Preterm birth in the general U.S. population occurs in 9% of all deliveries and preterm labor occurs in 16% of all pregnancies (Ventura, et al, 1993). This sample of 9.5% preterm birth and 13.6% preterm labor incidences reflects a slightly higher rate than expected for a group of very low risk, healthy women. The overall preterm birth and preterm labor incidences differ from other military studies and can partially be explained by a special type of Berkson's bias: overrepresentation of high risk active duty personnel going to major military medical centers contributing to prematurity rates (Buttemiller, 1984). Fox and associates (1977) found a 13% preterm labor rate at Wilford Hall, a major Air Force medical center compared to 6.3% preterm labor incidence a study of Air Force woman at Lackland Air Force Hospital (Hauth et al., 1983), 6.8% at Keesler Air Force Medical Center (although a Medical Center, obstetrics department did not normally handle high risk patients), and a 2.1% preterm labor at Naval Hospital Camp LaJeune (Magann & Nolan, 1991). This is in contrast to 14% preterm labor rate (with a 12% preterm birth rate) at Naval Medical Center Portsmouth (Spandorfer & Graham, 1996) and 11.9% preterm birth incidence at four major Army medical centers (Adams et al., 1995). Buttemiller (1984) sought to overcome this bias by accessing the United States Air Force medical data base at Brooks Air Force Base, studying 3,461 active duty women and found a preterm birth rate of 5.87%. However, Ramirez and associates (1990) still found a 9.9% preterm birth rate after accessing Army data bases of over 6000 Army women stored at Fort Sam Houston and the U.S. Army Military Personnel Center in Alexandria, Virginia. Although major medical centers were used in this study, again, most of the bias was eliminated by the fact that strict exclusion criteria were used (no prior history preterm birth, spontaneous abortion, chronic illnesses or diagnosed

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obstetrical complications) and a low risk sample was obtained prospectively. There were also the advantages of larger numbers of active duty women in one area and similar residency programs which would not have been found in low risk settings.

However, it was clinically significant that there was a lower rate of preterm labor and birth at Tripler. This could not be accounted for by race (25.9% were African American compared to 25.0% at San Diego, $\chi^2 = 11.21$, p=.737), marital status (62.1% were married compared to 66.3% at Portsmouth, $\chi^2 = 7.744$, p=.052) or rank (6.9% were officers at Tripler compared to 5.9% at San Diego which had the highest preterm birth rate). There were no significant differences in social support scores between the sites (F=.540, p=.655). Tripler is considered an overseas military site and candidates and their families are screened for health and emotional problems before given orders for duty at this Hawaii site. Separation Naval sea tours from Hawaii are much shorter than tours from the mainland United States (1-2 months and 9 months or longer, respectively).

Logistic Regression Analysis Hypothesis Testing In testing Hypotheses 2.1 to 2.4, logistic regression analyses were used to determine the odds of predicting preterm labor and preterm birth when fatigue or occupational fatigue were considered.

Preterm Labor

In initial bivariate testing, the preterm labor incidence in this sample did not significantly vary according to fatigue severity or occupational fatigue conditions. There was a trend toward a relationship of lower fatigue severity (t=1.807, p=.072) and proportionately higher number fatigued by posture in their jobs (t=1.548, p=.122) with



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preterm labor. When VAS-F (total of the 13 fatigue items) was dichotomized at 660 (scores above this were defined in this sample as 'high' fatigue), low fatigue was weakly rated to preterm labor (Chi square= 3.782, p=.052).

Most researchers have examined preterm birth rather than preterm labor due to the increased morbidity and mortality associated with the neonatal consequences of preterm delivery. Therefore, there are no other studies to compare this somewhat surprising relationship involving lower fatigue and preterm labor. With consideration of the trend of increased posture stressors with preterm labor in this study, possibly unmeasured sources of increased job activity level by the military women with lower fatigue levels could lead to uterine irritability and the start of cervical dilatation. Although Chi square analysis was not statistically significant (χ^2 =.807, p=.369), 61% of the 110 pregnant military women whose job involved standing greater than 3 hours (posture subscale on OFI) experienced low fatigue as opposed to 39.1% who were experiencing high fatigue. Occupational fatigue, hence, appeared to be protective for preterm labor. Those who ignored the fatigue warning signals went into preterm labor.

The tentative explanation of low fatigue and high activity with preterm labor is plausible, considering the trend of posture and preterm labor in this study. Previous studies have shown a connection between standing at work and adverse pregnancy outcome (Teitelman et al., 1991; Luke et al., 1995). In a study of 4259 employed women with singleton pregnancies at 16 weeks gestation (Henrikson et al., 1995), women walking or standing for more than 5 hours per day had an increased rate of preterm deliveries (OR=3.3, 95% CI 1.4-8.0). A dose response pattern was found: more hours of



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standing or walking, the higher the risk of preterm delivery. In none of these studies was fatigue measured using more than a one item question about fatigue level or the level of fatigue measured in relationship to occupational fatigue sources.

The association between preterm labor and low fatigue and posture disappeared in the multivariate model, suggesting that previous studies indicating a positive relationship did have methodological problems. The one other study (Pitzer et al., 1994) examining fatigue and pregnancy outcome demonstrated significantly different fatigue levels for women at risk for pregnancy complications compared to those at low risk for complications, but may have compared differences by socio-economic group. Although the design called for matching of subjects for race, age, week of gestation, level of education and parity, the 'at risk' group had significantly less education and income. Since only bivariate comparisons were done, controlling for socio-economic variables and other possible salient variables, such as smoking or stress levels, were not considered in the analysis.

Conflicting results from previous studies of posture may be due to the validity of the exposure measurement. Data about standing at work revealed positive relationships with adverse pregnancy outcomes for job titles (Naeye & Peters, 1982; Wohlert, 1989; Teitelman et al., 1990) or from retrospective reports (Berkowitz et al, 1983; Mamelle & Munoz, 1987; Saurel-Cubizolles & Kaminski, 1987; McDonald et al., 1988; Luke et al. 1995).

In a recent study examining posture and gestational outcome(Henriksen et al. 1996), the research design was prospective, used all working women, measured activity levels at 16 and 30 weeks GA and did control for potential confounders. Precision was £._

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compromised as some women were not able to separate periods of walking from periods of standing at work and the preterm birth rate was only 3.6%. This reduced the ability of the investigators to detect significant differences between variables; consequently, certain confounders could have influenced the results but there was insufficient statistical power to detect these differences.

Statistically significant variables noted in the final multivariate logistic regression model for preterm labor included low sleep disturbance, the officer rank and negative life events. Also, a significant interaction was noted between caffeine intake and fatigue severity. These main effects remained significant after controlling for ethnicity, age, hours work, exercise and smoking. Hemoglobin, a nutritional status variable, was added to the model because it had an effect on working nights, but its overall effect in the model was not statistically significant.

Sleep disturbance and officer rank have not been associated with preterm labor in previous studies. It may be that because both of these variables are associated with low fatigue they could be used as proxy measures of energy. A combination of low sleep disturbance and increased responsibility in a relatively homogenous population may increase exposure to ergonomic stressors (eg. prolonged standing, physical exertion and long work weeks) and increase risk for preterm delivery (Marbury, 1992). More detailed explanation of the relationship of officer rank and pregnancy outcome is found in the section on preterm birth.

Stress as defined by number of negative life events in this study has been addressed as being related to pregnancy complications in a number of studies (Newton et al., 1984; Berkowitz & Kasl, 1983, Mutale et al., 1991). Results are difficult to compare

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with this investigation as they represent different study designs (retrospective) and combined measures of complications (using both life events and negative attitude toward pregnancy). In a population based prospective study, 5834 woman completed questionnaires on life events, psychological distress, social support, occupational exposures and demographic information at two time periods—16 weeks and 30 weeks GA. Similar to this study, life events assessed by the subject as stressful, not just implied by the number of stressful events, was associated with shorter duration of gestation. Similar to this study, the association was uniform across age, marital status, education, smoking and intake of caffeine. Military pregnant women are thus at high risk for complications due to stressful events such as job changes, separation from spouses/partners (Holm, 1992) and pressure to maintain a level of fitness after pregnancy (Institute of Medicine, 1995) that they interpret as adverse. Social support (specifically that of the friend/relative of the respondent), conceptualized as a buffer to stressful life changes, was univariately related to preterm labor. But when social support was placed in the multivariate model with negative life events, it was no longer statistically significant, implying that it did not play as important a role as stress in modifying gestation duration.

Finally, fatigue severity was noted to have a significant interaction with caffeine intake. Fatigue in this study on preterm labor varied with caffeine intake. More specifically, as fatigue increased, the probability that the low caffeine intake group would have preterm labor decreased. It would appear that low caffeine intake with low fatigue is a marker for preterm labor. Pharmacologic properties of caffeine include stimulation of the central nervous system and cardiac muscle but relaxation of smooth muscles ř.,

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(Hinds et al., 1996). Since the uterus is smooth muscle, high caffeine intake may be related to decreased incidence of preterm labor. This would explain why it is that low caffeine rather than high caffeine, is related to preterm labor. This relationship was supported in a recent study (Pastore & Savitz, 1995) where lower intake of caffeine (1-150 mg/day) in the second trimester was related to preterm delivery (OR=1.6, 95% CI=1.1-2.3). With increased catecholamine release, the advantage of high caffeine intake may be negated when fatigue is high. In most studies (Larroque et al., 1993; Peacock et al., 1995), there is no relationship between caffeine and pregnancy outcomes but notably the investigators are comparing no intake to extremely high intake of caffeine (over 400 mg/day) and fatigue levels are not considered.

Low rate of weight gain during pregnancy univariately showed a trend of association (t=1.416, p=.13) to preterm labor. When placed in the multivariate model, it was no longer significant. However, with consideration of the concern pregnant military women have over weight gain and the fact that gestational age was taken into account for total weight gain (eliminating the bias of shorter gestation), this was a clinically important finding. Women with preterm births averaged 0.86 pounds weight gain per week as opposed to women with term deliveries who averaged 0.94 pounds. Future studies with larger sample sizes (and larger number of cases of preterm labor) may be able to statistically establish this relationship.

Preterm Birth

Neither fatigue severity, occupational fatigue, nor any of the related variables such as hours of work per week, were associated with preterm birth. The power analysis calculated for this study used an effect size of 0.3 when, in fact, the effect size was 0.1. It 1. 1

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would appear that the assumption that fatigue is a proxy variable for employment activity is not true. In either case, there was insufficient statistical power due to the small number of cases (n=34) to show a relationship between fatigue and preterm birth. The research design discussion accounting for lack of statistical significance noted above for fatigue and posture and preterm labor could also apply for preterm birth as an outcome.

When other variables were examined for entry into a logistic regression model, only the officer rank variable and one interaction—negative life events and sleep disturbance—were significantly related to preterm birth. Controlling for potential confounders-- ethnicity, age, hours work, negative life events, exercise, smoking and social support—did not change the unadjusted estimates of the association.

Twenty-six percent of the active duty women of officer rank delivered prematurely compared to 7.2% of the enlisted women. Although officers have been included in studies of pregnant military women in the past (Fox et al., 1977; Buttemiller, 1984), most have deliberately excluded this group to decrease "variation in socioeconomic status" (Messersmith-Heroman et al., 1994, p.577; Adams et al., 1995) or because officer occupations had not been analyzed for physical demand requirements (Ramirez et al., 1990). In one study, officers were included in the study to differentiate socio-economic status (Buttemiller, 1984). The rate for enlisted personnel (5.78%) in that study was nearly one percentage point lower than that of commissioned officers (6.73%). The fact that this finding was not statistically significant indicated that rank may not be an adequate determinant of socio-economic status. It is also possible that, in the military, even officers may have jobs perceived as "high demand and low control" which have been associated with preterm birth (Homer et al., 1990). The military 1:



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bureaucracy may give the officer a great deal of responsibility, but they must still answer to a chain of command which may provide an atmosphere of pressure to perform.

The one significant interaction for this regression indicated that the effect of sleep disturbance on preterm birth varied with the number of negative life events experienced. More specifically, decreased sleep disturbance has little effect on preterm birth for those with fewer negative life events. But less sleep disturbances increase the incidence of preterm birth for those with a high number of negative life events. Although there was no statistically significant relationship between fatigue variables and preterm birth, based on the relationships found with preterm labor (predecessor of preterm birth), it would appear that low fatigue (the result of low sleep disturbance) could also be associated with preterm birth if this study had more statistical power with more cases of preterm birth. Summary for Preterm Labor and Birth

In summary, when history of preterm birth, spontaneous abortion, access to prenatal care, and education are controlled through design and sampling healthy active duty women and ethnicity, age, hours work, exercise and smoking are controlled statistically, there appear to be three major areas related to preterm labor and birth. Low perceived fatigue was related to preterm labor. Correlates of variables for low fatigue include low sleep disturbance with low caffeine intake as an effect modifier and, potentially, the officer rank. Other variables possibly contributing to low fatigue are married marital status and no children in the household. A second major area is stress estimated by the number of negative life events and poor nutrition (low hemoglobin and poor rate of weight gain). A third area is occupational stress due to the standing posture and working nights. R

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Ethnicity and smoking are two variables found repeatedly in previous studies to be related to preterm birth and labor (DeHaas et al., 1991; Peacock et al., 1995; Hartikainen-Sorri & Sorri, 1989; Mercer et al., 1996; Guinn et al. 1994; Shiono & Klebanoff, 1986; Hogue & Hargraves, 1995; McCormick et al., 1990) and were not associated with preterm labor or birth in this sample. Six percent of the sample admitted to currently smoking at 22-26 weeks GA. This small number may have decreased the statistical power to detect any associations with a relatively rare pregnancy outcome.

In regard to ethnicity, national statistics (Ventura et al., 1993) indicate that 18.2% of African Americans and 9.3% of Whites deliver before 37 weeks gestation. In this sample, more White service women had preterm births (10.6%) compared to African American women (8.2%). This agrees with another analysis of service women (Adams et al., 1993) where White service women had a somewhat higher rate of preterm delivery than would have been expected by their demographic characteristics, and African American women had 10% less than would have been expected in the general U.S. population. Non-occupational role demands were not associated with preterm labor and birth; this was also supportive of previous studies (Berkowitz et al. 1990; Hickey et al., 1995). The fact that all the women were employed and had access to medical care may explain the ethnic differences in these outcomes and that more married women had preterm labor and deliveries in previous studies (Berkowitz & Papiernik, 1993; Gjerdingen, 1992; Bragonier et al., 1984). Overall, the very few risk factors identified in low risk pregnancies similar to this sample explain only a small fraction of preterm delivery incidence (Harlow et al., 1996).

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Repeated Measures Analyses

In testing Hypotheses 3.1 to 3.4, repeated measures analyses of variance (RMANOVA) were conducted to test the interaction between time and condition (preterm labor or birth) depending on the treatment (fatigue or number of hours worked).

Similar to the single measurements of fatigue at clinic visits at 22-26 weeks GA, repeated measures of fatigue using a different but concurrently valid fatigue measurement tool, the Pearson-Byars confirmed that fatigue at different times of the day was also not related to preterm labor and birth. All women averaged about the same level of fatigue during the day—lowest in the morning and at midday and the highest in the evening. This is first time fatigue has been measured in this manner in the second trimester over consecutive work days. In a previous study using the Pearson-Byars instrument to measure fatigue six times over 24 hours (Van Lier et al., 1992) in the first trimester, a pattern of fatigue was not noted as the fatigue scores were summed. However, similar to this study of healthy, low sleep disturbed women. Lee and associates (1991) found higher levels of energy after a period of sleep in normal (no sleep difficulties) pregnancy. This finding has implications for timing of administration of fatigue measures and the need for additional information regarding the time of sleep periods in relation to data collection. It is also important to note that there was no special pattern of fatigue on work days that differed for preterm labor and birth cases from term deliveries. Fatigue was averaged at specific times of the day (morning, midday and evening) over the two work days and the difference between average evening and fatigue over two days was attained. There was still no difference between fatigue and either preterm labor or birth.

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Hours of work per week, as a proxy measure of occupational stress and fatigue, has been associated with preterm birth in previous studies (Luke et al., 1995; Peoples-Sheps et al., 1991). Increasing mean hours of standing and increasing mean hours of walking also had a tendency of increasing preterm delivery (Henriksen et al. 1995). A number of studies have defined "employed' women as those who work sometime during their pregnancy—sometimes just the first trimester (Saurel-Cubizolles et al., 1990), work 30 or more hours per week at the time of conception and, until at least 28 weeks GA, or work a number of hours during an unspecified time of pregnancy (Peoples-Sheps et al., 1991; Messersmith-Heroman et al., 1994; Luke et al., 1995).

What is significant in this sample is the fact that preterm and term labor and delivery respondents worked similar numbers of hours at the 22-26 weeks GA measurement period. RMANOVA indicated a faster decrease in number of hours worked for preterm labor and birth respondents due to early deliveries and treatment of preterm labor with bedrest. Consequently, there was a significant difference in work hours between preterm and term groups. Results of retrospective studies, where women who delivered premature infants try to remember their hours of work throughout pregnancy, need to be viewed with caution. Although Hypothesis #3.2 was supported, the reason there was a difference in work hours between term and preterm respondents was largely due to a 'treatment effect' for preterm labor. Hours of work per week may not be a valid measure of occupational stress if measured in the third trimester even with a military sample where over 95% worked after 32 weeks GA as compared to 75% in the civilian population (Colie, 1993).

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Strengths and Limitations of the Study

Strengths

There are several strengths of this study. First, there is support for the internal consistency reliability and concurrent validity of the VAS-F. Fatigue was also measured over two consecutive work days, demonstrating the diurnal nature of fatigue while maintaining the same relationship the VAS-F had with preterm birth and labor. Some of the instruments, such as the Sleep Disturbance Scale and Norbeck's Life Events Questionnaire, were psychometrically strong and relevant to the population studied, enhancing the link between constructs. (Waltz et al., 1991).

Bias was minimized in a number of ways by the design of this study. First, the study was prospective, thereby minimizing recall bias which was a major weakness of numerous previous studies where recall of fatigue was sometimes as long as ten years. The VAS-F was administered based on fatigue levels "right now," and the fatigue diary was completed as the women were experiencing fatigue during two consecutive work days. This may not have occurred in every instance but this was better than purposefully having women recall fatigue from 6 time periods from the day before as in the nausea/fatigue study (Van Lier et al., 1992). Most instruments asked for self report of symptoms "right now" or, at the longest, within the last three months. Strict inclusion criteria minimized some major confounders for preterm labor and birth such as history of preterm birth, multiple gestation, history of induced abortion, teen pregnancies and chronic illnesses. Yet, independent variables that needed to be measured such as tobacco, alcohol and caffeine exposure (common substances taken in a military population) and officer rank (most recent studies have only examined enlisted women) and role demands

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(non-occupational) were kept in the study. The confounders of socio-economic status, substance use and ethnicity were limited by the inherent nature of a military population with excellent access to care (Adams et al., 1993), minimal substance use (Polzin et al., 1991) and where the 2:1 preterm birth to term birth ratio between African Americans and Whites did not hold (Hogue & Hargraves, 1995).

The study was conducted on samples of military women on the east coast, west coast and in Hawaii, increasing the generalizability of the results to the population of military women. Return of diaries and follow-up of respondents was over 90% and missing data were minimized by careful examination of questionnaires by research assistants for completeness. The timing of data collection at 22-26 weeks was before most women go into preterm labor or deliver. There were very few refusals in the clinics where enrollment was conducted; many subjects expressed much interest in the research. Limitations

Several limitations exist in the administrative handling of the Research Assistants (RA's), data collection, sampling, precision of some of the instruments and restrictions caused by the population and model selected for the study. This was a large, complicated study for a relatively inexperienced doctoral student to conduct even with substantial funding from a TriService grant award. There were 2 RA's in San Diego, 4 in Hawaii, and 6 in Norfolk, Virginia. It was a challenge to ensure that all were properly trained, were reliable in their screening of potential participants and administration of instruments and that all could keep up with the longitudinal telephone follow up portion of the study. Subjects needed to be reminded about turning in fatigue diaries. Added time was needed

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for another training session with the RA's for conducting postpartum chart reviews. In total, it took 15 months for all the data to be collected on 359 subjects.

Although consecutive sampling was the method selected for this study, it was only followed in San Diego and Travis Air Force Base. In San Diego, two full time RA's covered 3 clinics at all hours the clinics were open from Monday to Friday. Clinic staff were very cooperative in identifying potential candidates for the study. At Travis, the principal investigator (PI) also received cooperation from the clinic staff. If the PI was not able to drive to the site on a respondent's appointment day, the local PI at the site was willing to screen and enroll subjects and administer questionnaires. In Hawaii and Portsmouth, however, the RA's did not work full time on the study and, consequently, the enrollment at those sites was by convenience sampling as screening and enrollment coverage at the clinics could not be done everyday. Consequently, those participating in the study may have been more willing to help in a study or happen to prefer appointments on the day the RA's were available to enroll them in the study.

Results of this study are based on a sample size that was calculated a priori via a power calculation. Effect size was based on previous knowledge of a 8% preterm birth rate. It appeared that 34 (9.5%) women who delivered preterm provided inadequate power to study the relationship of fatigue to preterm birth. However, with 50 service women (13.6%) diagnosed with preterm labor, there appeared to a tentative relationship to fatigue.

Some of the instruments lacked the precision needed to accurately measure certain constructs. The Occupational Fatigue Index, for example, did not fit the sample being studied. Only a few women worked on industrial machines. The other sources of occupational fatigue needed more detailed descriptions to more readily fit the types of jobs performed by military personnel. For instance, "posture" should have included exact number of hours of standing, stooping and stretching. Many of the women stated that Mamelle's definition of mental stress (repetitive work) did not fit what they envisioned as mental stress (eg. high demand, low control job) as described in a National Longitudinal Survey of Labor Market Experience (Homer et al., 1990). The moderate and strenuous exercise and role demand tools were open-ended and, consequently, a number of women could have exaggerated the number of hours spent at each task. For instance, some women confused exercise time with strenuous activity on the job, claiming 4-8 hours of strenuous exercise 7 days a week. Some claimed that they spent time maintaining an adult relationship—"all the time." This needed to be clarified on data entry. Fortunately, RA's at each site, on telephone follow up were able to question respondents when there was confusion on some of the questionnaires. Nevertheless, due to answers on questionnaires ranging 3 standard deviations beyond the mean, the exercise and role demand needed to be truncated and changed from continuous to categorical data in order to meet assumptions of statistical tests.

Except for hemoglobin at 28 weeks, no other objective physiological data were collected. With 36% of the variance for fatigue explained in the linear regression analyses, there is still 64% left unexplained. It would appear probable that specific physiological measures such as urine catecholamine measurement (Katz et al., 1991) for stress levels and activity levels from wrist actigraphs monitoring (Patterson et al., 1993) could account for additional unexplained variance in fatigue. In addition, data from the

self-reported sleep disturbance scale could be further validated by sleep encephalography on a randomly selected number of service women in their homes.

The RA's were instructed to administer the instruments in a set order. Occupational Index (OFI) was administered after the 82-item Life Events Questionnaire (LEQ). Respondents may have more been fatigued with instruments administered last Therefore, results of the OFI and possibly the LEQ (due to its length) should be viewed with caution.

Since the active duty military woman is a member of a relatively homogenous population with special protection by policy (see Appendix I), enabling easy access to health care, special privileges of housing, enjoying the security of employment, good health and physical fitness, the generalizability of these results to all pregnant women is limited. Employment of childbearing women, however, continues to rise and, therefore, certain aspects of this study can be applied without the confounding aspects of differences in socio-economic group.

Finally, the environmental demands framework for this study, with demographic variables found in both internal and external portions of the model, restricted the fatigue analysis. Personal characteristics such as age and marital status, for example, could not be controlled in the first step of a regression analysis because the model implied that internal and external demands needed to be kept together. Also the environmental demands model implies that symptoms originating in the internal and external environment are unidirectional. Certain behaviors such as caffeine intake appeared to change as the level of fatigue increased. A recent update of the theory of unpleasant symptoms contains a proposal where 'performance' (eg. preterm labor) has a reciprocal

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relationship to symptom experience (Lenz et al., 1997). Certain demands in the model have significant interactions and some, such as sleep disturbance and negative life events, actually cross over between the internal and external environment of the pregnant woman.

Implications for Nursing

Due to the relatively low incidence of fatigue in an actively employed population and lack of association with preterm labor and birth, the health care provider needs to attend more to the employed healthy woman who may be taking on additional responsibility because she "feels so good." Careful questioning of what life changes have occurred, their impact, and what the woman is doing to deal with these changes may be appropriate in light of the relationships these changes have with preterm labor. With the military woman, these changes would have to do with eating, sleeping, changes in relationships with employers or partners, and financial difficulties due to recent purchases. Stress leading to preterm labor may also be secondary to inadequate diet. Therefore, much attention needs to be focused toward weight gain and changes in hemoglobin/hematocrit at each prenatal check. Discussions with each active duty woman regarding her concerns about returning to her pre-pregnant weight within 6 months after delivery, along with passing the physical exam, need to be made. Questions about caffeine intake (eg. less1-2 cups of caffeinated coffee per day) need to be made at each visit. Low caffeine intake and low fatigue may be a marker for early onset of labor. Despite its possible smooth muscle relaxation properties, high caffeine intake (eg. greater than 4 cups of caffeinated coffee per day) probably should not be recommended.

In terms of occupational fatigue, the trend of posture (>3 hours per day of standing, stooping and stretching) and working nights in association with preterm labor

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suggests counseling about rest periods in the recumbent sidelying position to increase uteroplacental circulation. Recommendations to commanders with pregnant women in their units could include re-assignment to day or evening shift after 22-26 weeks GA and a work schedule where periods of standing longer than 3 hours and unusual postures are avoided. However, total hours of work may not be necessarily restricted. The status quo, not more than 48 hours per week as written in Air Force Regulations (see Appendix I) is adequate. There is little scientific basis for decreasing hours per week with increase in gestational age as long as rest periods are provided.

In addition to the clinical implications for nursing, theoretical nursing implications call for an extension of the respecification of the environmental demands model for second trimester fatigue in pregnant military women (see Figure 4.1) and for preterm labor and birth (see Figure 5.1). Similar to results of study of non-pregnant women (Lee et al., 1994), internal environmental demands take on a more important role than external demands in influencing fatigue levels in the second trimester fatigue model. This is not as evident in the preterm labor and birth environmental demands model as external demands such as occupational rank, occupational conditions and negative life events take on more significant roles in predicting pregnancy outcome. In addition, the model contains bi-directional relationships between the various demands and, with negative life events, the nutritional demands (hemoglobin and weight gain) and occupational posture, more direct links between demands and preterm labor and birth.

Future Directions for Research

This study has provided descriptive and analytic information about fatigue in pregnant active women and the association of fatigue and sources of occupational fatigue with preterm labor and birth. Due to surprising results showing a trend toward low

Figure 5.1: Respecification of Model of Environmental Demands for Pregnant Military Women in Relating Fatigue to Preterm Labor and Birth



= interactions or tentative relationships

- = significant relationships

fatigue and preterm labor and birth, conceptually this means that fatigue in healthy populations continues to demonstrate a protective function and further investigation of

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how to best use this finding to enhance pregnancy outcomes is important. Areas of future inquiry follow.

This research suggested that depression, sleep disturbance, negative life events and role demands influence fatigue severity and, additionally, that strenuous exercise, age and marital status, influence vigor. Instrument limitations for depression (based on five items of the POMS) and role demands and exercise decreased measurement precision for these variables. The PI chose shorter versions of instruments because of concern that a lengthy questionnaire packet would exhaust the participants. Future measurements of depressive symptoms could be done by a 20 item Center for Epidemiologic Studies-Depression Scale (CES-D) which does not directly mention fatigue or pregnancy-related symptoms in any of the 20 items. Instead of open questions for role demands and exercise, specific limits on hours per week in a Likert scale format and very clear wording that the demands and exercise did not occur on work time, could be tested in pilot studies for reliability and validity. A dose-response relationship between role demands and exercise and fatigue can be made; a relationship important for calculating a potential causality effect. In addition, activity levels could be objectively estimated at work, home and under leisure time exercise using dual-mode actigraphy to determine level of exertion with each type of activity. This instrument, which measures motion in two modes: zero-crossing mode (ZCM) for frequency of movement and time-abovethreshold (TAT) for duration of movement has been tested to differentiate movement in active and sedentary young adult (Patterson et al., 1993) as well as differentiating between light, moderate and heavy levels of activity intensity (Leidy et al., 1997). Electroencephalograms of sleep disturbance patterns, though providing a more objective

pattern of sleep problems, may not be appropriate for study with this population as the relatively rare occurrence of preterm birth examined prospectively would make the study prohibitively expensive.

The Occupational Fatigue Index (OFI) did not adequately measure exertion leading to fatigue in this prospective study of healthy active duty pregnant women who tended to work long hours per week and longer into their pregnancy (over 80% were still working at term). The two studies which used the OFI and showed a statistically significant relationship between the OFI and preterm birth were retrospective in design (Luke et al., 1995; Mamelle et al al., 1984). In prospective studies which showed statistical significance (Henriksen et al., 19195; Ahlborg et al., 1990; Florack et al., 1995), only specific subscales were significant such as heavy lifting or long periods of standing. This did not include studies which just looked at job titles rather than asking women about their sources of fatigue during pregnancy (Teitelman et al., 1990; Ramirez et al., 1990). The other prospective and retrospective studies did not detect a relationship between occupational fatigue and preterm birth (Brandt & Nielsen, 1992; Klebanoff et al., 1990; Zuckerman et al., 1985; Berkowitz et al, 1983; Hickey et al., 1995). Future research could include tool development of occupational fatigue factors which could prospectively predict preterm. Methodology for this tool development could include critical incident interviews of pregnant active duty and full time employed nurses (or other civilian workers not part of lower socio-economic groups such as members of hospital housekeeping departments). The tools could include hours spent in standing position or exposed to physical exertion as opposed to tools which measured dichotomous exposure levels.

This sample represents a population of healthy pregnant women (enlisted and officers) with good access to health care which provides a biased view of fatigue faced by other healthy pregnant women who may not have the security of free health care. This factor limits generalizability of findings to other employed women in similar circumstances. The fatigue experience as well as the prediction of preterm labor and birth may be different in civilian women with similar employment and medical insurance circumstances. Civilian employees have a range of responsibility and job characteristics in terms of demand and control (Homer et al., 1990) as in the military. A replication of this study with a matched sample of civilian workers could increase the generalizability of the findings.

Officers need to be examined closely for factors which may lead to adverse pregnancy outcomes. Unfortunately, as yet unidentified factors associated with preterm labor and birth appear to be associated with the increased responsibility of commissioned officer status despite their higher socio-economic status. Analysis of this group showed that 77% of officers either smoked or quit earlier in pregnancy as opposed to only 58.8% of enlisted women (χ^2 =4.341, p=.037). It appears from this research that higher fatigue was protective for enlisted women while low fatigue was a risk factor for officers for preterm labor. More research needs to be done specifically examining these factors and other potential variables which characterize officer status and its association with adverse pregnancy outcome.

Finally, with low fatigue having a tentative relationship with preterm labor, it becomes important to look at factors which enhance energy levels and how these factors

affect perinatal performance. One such factor is exercise. Previous studies have shown that certain forms of moderate physical activity may actually protect against preterm deliveries (Berkowitz et al. 1983). Clapp and associates (1993) reported on 120 women who exercised regularly during the second and third trimester. No increase in uterine activity was noted during or after exercise. All of these women were well conditioned and exercised regularly, but neither fatigue nor nutritional variables were measured. Women who may be healthy but do not exercise regularly (47% of the active duty military did not do strenuous exercise in this study and 28% did not exercise at all), and women whose nutritional levels may be compromised (7.7% of the present sample had hemoglobin levels less than 10 mg/dl) may be at increased risk for preterm labor and birth. These women should be specifically identified for future studies.

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Appendix A

Informed Consents - University of California, San Francisco Naval Medical Center, San Diego Naval Medical Center, Portsmouth David Grant Medical Center, Travis Air Force Base Tripler Army Medical Center

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO CONSENT TO BE A RESEARCH SUBJECT

A. PURPOSE AND BACKGROUND

CDR Janice C. Stinson, NC, USNR and Kathryn A. Lee, PhD are conducting a research study to investigate the relationship of my work schedule, how I feel and my childbirth experience. I am being asked to participate in this study because I am a pregnant woman in the military.

B. PROCEDURES

If I agree to be in this study, the following will happen:

1. At the prenatal clinic, I will be asked to complete questionnaires measuring how I feel, what my job is like, recent changes in my life, social and family support, my experiences with eating and sleeping at this time in my pregnancy.

- 2. I will fill out a diary which will measure how I feel upon awakening, at midday and at
 - bedtime for two consecutive work days and return it to the investigators in a stamped envelope

3. The investigators will examine the hospital record of my baby's delivery to obtain information about the delivery

4. I will get a monthly telephone call from one of the investigators or research assistant who will be ask me about job changes and the number of hours I worked per week during the month

Participation in the study will take about 60-75 minutes over a period of 1-5 months depending on the length of my pregnancy

C. RISKS/DISCOMFORTS

1. I may feel uncomfortable with some of the items on the questionnaires, two day diary or questions during the telephone call. If any of the questions in the questionnaire, diary, or telephone calls make me uncomfortable, I can refuse to answer the question or stop the study at any time.

2. Confidentiality: Participation in research may involve a loss of privacy; however, my records will be kept as confidential as possible. The study information will be coded and kept in a locked file at all times. Only CDR Stinson and Dr. Lee will have access to the files. No individual names will be used in any reports or publications that may result from this study.

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D. BENEFITS

There is no direct benefit to me from participating in this study. However, the information I provide may help future working pregnant women in the prevention of preterm delivery.

E. COSTS

There will be no costs to me as a result of taking part in this study.

F. REIMBURSEMENT

I will not be paid to participate in this study.

G. ALTERNATIVES

If I choose not to be in the study, I will continue to receive all regular care.

G. QUESTIONS

I have talked to CDR Stinson or Dr. Lee about this study and have had my questions answered. If I have further questions about the study, I may contact Ms Stinson at (510) 769-8961 or Dr. Lee at (415)476-4442. If I have any comments or concerns about participating in this study, I should first talk with the co-investigator, CDR Stinson. If, for some reason, I do not wish to do this, I may contact the Committee on Human Research, which is concerned with the protection of volunteers in research projects. I may reach the committee office between 8:00 a.m. and 5:00 p.m. Pacific Time, Monday through Friday by calling (415) 476-1814 or by writing: Committee on Human Research, Box 0962, University of California, San Francisco, San Francisco, CA 94143.

J. CONSENT

I will be given a copy of this consent form to keep. PARTICIPATION IN RESEARCH IS VOLUNTARY. I

am free to decline to be in this study or to withdraw from it at any point. My decision as to whether or not to participate in this study will have no influence on my present or future status as a member of the military, and as a patient.

Date

Signature of Study Participant

Date

Signature of Person obtaining signature

5-23-95

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NAVAL MEDICAL CENTER SAN DIEGO, CALIFORNIA 92134-5000

CONSENT BY A SUBJECT FOR VOLUNTARY PARTICIPATION IN A CLINICAL INVESTIGATION (RESEARCH) STUDY

_____, have been asked tovoluntarily 1. I, participate in a research project entitled, "Association of Fatigue and Preterm Birth in Active Duty Military Women, " being conducted at the Naval Medical Center, San Diego by medical researchers from the Departments Obstetrics and Gynecology and Patient Administration in collaboration with Naval Medical Center, Portsmouth, Tripler Army Medical Center, and David Grant Medical Center, Travis Air Force Base.

2. I understand that the purpose of this research project is to investigate the relationship of my work schedule, how I feel, and my childbirth experience. I am being asked to participate in this because I am a pregnant woman in the military,

3. I understand that my participation in this research project will be for a period of one week to five months depending on the length of my pregnancy.

4. The procedures for this project include:

a. At the prenatal clinic, I will be asked to complete questionnaires measuring how I feel, what my job is like, recent changes in my life, social and family support, my experiences with eating and sleeping at this time in my pregnancy;

b. I will fill out a diary which will measure how I feel upon awakening, at midday and at bedtime for two consecutive work days and return it to the investigators in a stamped envelope;

c. the investigators will examine the hospital record of my baby's delivery to obtain information about the delivery; and

Subject's Initials:

CPHS/IRB Approval Stamp/Seal Required

No. of pages: 4 1-May-97



Fatigue & Preterm Birth/Active-Duty Women; Stinson, J. CIP #S-95-091

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d. I will get a monthly telephone call from one of the investigators or research assistant who will ask ms about job changes and the number of hours I worked per week during the month. I will be asked to tabulate this information so I can give it to the investigator when he/she calls.

5. A total of 350 subjects are Expected to participate in this study, of whom up to 155 may be from Naval Medical Center, San Diego.

6. I understand that I may feel uncomfortable with some of the items on the questionnaires, the two-day diary or questions during the telephone call. If any of the questions in the questionnaires, diary or telephone calls make me uncomfortable, I can refuse to answer the question or stop the study at any time.

7. I understand that my participation in this research project may or may not be of direct benefit to me personally. However, the results of this study may help the investigator gain important knowledge about fatigue and occupational fatigues and the incidence of preterm birth in active duty military women or aid in the future medical evaluation or treatment of other patients.

8. If I choose not to be in the study, I will continue to receive all regular care.

9. In all publications and presentations resulting from this research study, information about me or my participation in this project will be kept in the strictest confidence and will not be released in any form identifiable to me personally. However, I realize that authorized personnel from the Navy, Army or Air Force Medical Departments may have access to my research file in order to verify that my rights have been adequately protected.

10. If I suffer any injury directly related to my participation in this research study, immediate medical attention is available at the Naval Medical Center, San Diego, or at another closer military medical treatment facility, if applicable, I understand that although no financial compensation is available, any injury

Subject's Initials:

CPHS/IRB Approval Stamp/Seal Required



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Fatigue & Preterm Birth/Active-Duty Women; Stinson, J.

213 resulting from my participation in this study will be evaluated and treated in keeping with the benefits or care to which I am entitled under applicable Navy, other Department of Defense, and other state or Federal regulations.

11. If I have any questions regarding this research study, I may contact CAPT Janice Stinson at (510) 769-8961. If I have any questions about my rights as an individual while participating in a research study at the Naval Medical Center, San Diego, I may contact CDR Dean Gubler, MC, USN, Chairman, Committee for the Protection of Human Subjects at (619) 532-8125, or CAPT Charles Gray, MC, USN, Department Head, Clinical Investigation Department at (619) 532-8127. I may also call the Committee on Human Research which is concerned with the protection of volunteers in research done by investigators from the University of California, San Francisco. I may reach this committee by calling between 0800 and 1700, Pacific Time, Monday through Friday, by calling (415) 476-1814 or by writing: Committee on Human Research, Box 0962, University of California, San Francisco, San Francisco, CA 94143. If I believe that I have been injured as a result of my participation in this research study, I may contact LT M.C.L. Horrigan, JACG, USN, Naval Medical Center, San Diego, Legal Department, at (619) 532-6475.

12. I understand that my participation in this project is entirely voluntary and that my decision not to participate will involve no penalty or loss of benefits to which I am entitled under applicable regulations. If I choose to participate, I am free to ask questions or to withdraw from the study at any time. If I should decide to withdraw from the research project, I will notify CAPT Janice Stinson at (510) 769-8961 to ensure my timely removal from the study. My withdrawal will involve no prejudice to my future health care or any loss of rights or benefits to which I am otherwise entitled. Any new significant finding developed during the course of this study which might affect my willingness to continue participation will be communicated to me.

13. I have been informed that there will not be additional costs to me if I choose to participate in this project.

Subject's Initials:

CPHS/IRB Approval Stamp/Seal Required



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214 14. I understand that I am making a decision whether or not to participate in the research project described in the preceding sections subject to the conditions of participation described above. My signature indicates that I have decided to participate, having read and understood the information presented above and having been given the opportunity to ask any questions that I might have about the research study or my participation in the study. Further, my signature indicates that I have been provided with a copy of this consent document and a copy of a locument entitled, "California Experimental Subject's Bill of Rights."

SIGNATURES AND DATE SIGNED: PRINTED OR TYPED IDENTIFICATION:

Patient / Subj	ect (Date)	Name / Status / Sponsor's SSN
litness	(Date)	Name / Grade or Rank / SSN

Researcher/Investigator(Date) Name / Grade or Rank / SSN

DATE J

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PRIVACY ACT STATEMENT

1. Authority. 5 USC 301

2. <u>Purpose</u>. Medical research information will be collected to enhance basic medical knowledge or to develop tests, procedures, and equipment to improve the diagnosis, treatment, or prevention of illness, injury, or functional impairment.

Use. Medical research information will be used for 3. statistical analysis and reports by the Department of the Navy, the Department of Defense, and other U.S. Government agencies, provided this use is compatible with the purpose for which the information was collected. Use of the information may be granted to non-Government agencies or individuals by the Chief, Bureau of Medicine and Surgery in accordance with the provisions of the Freedom of Information Act.

4. <u>Disclosure</u>. I understand that all information contained in this Consent Statement or derived from the medical research study described herein will be retained permanently at Naval Medical Center San Diego and salient portions thereof may be entered into my health record. I voluntarily agree to its disclosure to agencies or individuals identified in the preceding paragraph. I have been informed that failure to agree to such disclosure may negate the purposes for which the research study was conducted.

SIGNATURES AND DATE SIGNED: PRINTED OR TYPED IDENTIFICATION:

(if Applicable)

Patient / Subject (Date) Name / Status / Sponsor's SSN

Parent / Guardian (Date) Name / Status / SSN (if Applicable)

Witness

(Date)

Name / Grade or Rank / SSN

NAVAL MEDICAL CENTER PORTSMOUTH, VIRGINIA 23708

INSENT FOR VOLUNTARY PARTICIPATION IN A CLINICAL INVESTIGATION STUDY

DATE _____

I, (<u>Name of Participant</u>), have been asked to voluntarily participate in a <u>research project</u> entitled, (<u>Association of Fatigue and Preterm Birth in Active Duty Military Women, research protocol</u> <u>number P-95-L-H000000-030 N</u>) being conducted at (<u>Naval Medical Center Portsmouth</u>).

The <u>purpose of this project is to</u> investigate the relationship of my work schedule, how I feel and my childbirth experience. I am being asked to participate in this because I am a pregnant woman in the military.

I understand my participation in this research project will be for the duration of my pregnancy.

The procedure for this project involves the following

 At the prenatal clinic. I will be asked to complete questionnaires measuring how I feel, what my job like, recent changes in my life, social and family support and my experiences with eating and sleeping this time in my pregnancy and return them to the investigators. This will take about 30-45 minutes.
I will fill out a diary which will measure how I feel upon awakening, at midday and at bedtime for

o consecutive work days and return it to the investigators in a stamped envelope

3. The investigators will examine the hospital record of my baby's delivery to obtain information about edelivery.

4. I will be getting a monthly telephone call from one of the investigators or research assistant who will k me about job changes and the number of hours I worked per week during the month

A total of <u>380</u> subjects are expected to participate in this project of which 150 will be recruited from Naval Medical Center, Portsmouth

I may feel like not answering some of the items on the questionnaires, two day diary or questions during the telephone call. I can refuse to answer the questionnaires, diary, answer the telephone calls or stop the study at any time.

I understand that this research may not help me personally but that the results may help the investigator learn about <u>determining the association of fatigue and occupational fatigue and preterm</u> birth in active duty military women or aid in the treatment of other patients.

If I choose not to be in the study, I will continue to receive all regular care.

In all publications and presentations resulting from this research project, my anonymity is guaranteed; although, I realize that authorized Navy Medical Department personnel may have access to my research file in order to verify that my rights have been safeguarded

Patient's/Subject's initials

INFORMED CONSENT FORM PAGE 2

. Taking questionnaires and the telephone follow ups will not involve risks to the fetus. However, if I suffer any physical injury as a result of my participation in this study, immediate medical treatment is available at Naval Medical Center, Portsmouth. I understand that although no compensation is available, any injury as a result of my participation will be evaluated and treated in keeping with the benefits or care to which I am entitled under applicable regulations.

- . If I have any questions regarding this research project, I may contact CDR Janice Stinson at (510) 769-8961 or CDR Bennett C. Leshnover at (804) 398-5787. For any questions regarding my rights as an individual while participating in a clinical investigation program at Naval Medical Center, Portsmouth, I can contact the Chairperson of the Institutional Review Board at (804) 398-5939 or Committee on Human Research, University of California, San Francisco between 0800 and 1700, Pacific Time, Monday through Friday by calling (415) 476-1814 or by writing, Committee on Human Research, Box 0962, University of California, San Francisco, CA 94143.
- ". I understand that my participation in this project is voluntary and that my refusal to participate will involve no penalty or loss of benefits to which I am entitled under applicable regulations or my present or future status as a member of the military. If I choose to participate, I am free to ask questions or to withdraw from the project at any time, I will notify CDR Janice Stinson at (510) 769-8961 to ensure an orderly termination process. My withdrawal will involve no loss of benefits to which I am entitled.
- 3. I have been informed that there will not be additional costs to me if I choose to participate in this project.
- 4. Any new significant findings developed during the course of the research which may affect my willingness to participate further will be explained to me.

certify that I have received a copy of this consent form.

Subject's/Patient's Initials

ate Signed

Paylent/Subject Signature

vitness' Signature & Date

Investigator's Signature & Date

Vitness' Typed Name - Rank - SSN

Investigator's Typed Name-Rank - SSN
INFORMED CONSENT DOCUMENT

60TH MEDICAL GROUP David Grant Medical Center 101 Bodin Circle Travis AFB, CA 94535-1800

Privacy Act of 1974 applies. DD Form 2005 filed in Clinical/ Medical Records.

PRIVACY ISSUES: Records of my participation in this study may only be disclosed in accordance with federal law. Including the Federal Privacy Act, 5 USC 552a, and its implementing regulations. DD Form 2005 contains the Privacy Act Statement for the records. I understand that records of this study may be inspected by the U.S. Food and Drug Administration (FDA), the sponsoring agency and/or their designee, if applicable.

TITLE OF STUDY

Association of Fatigue and Preterm Birth In Active Duty Military Women.

INVESTIGATORS' NAMES, DEPARTMENTS, PHONE NUMBERS

CDR Janice Stinson, NC, US Navy Reserve, Naval Hospital Oakland 220, San Bruno, (510) 769-8961 Dr. Kathryn Lee, University of California, San Francisco, Family Health Care Nursing, (415) 476-4442 Lynn Bricca, Major, USAF, NC, OB-GYN Clinic, (707) 423-5410

PURPOSE OF STUDY

(Th's section will explain the nature purpose(s) approximate number of subjects, and the duration of participants' involvement.)

I, ______, understand that I am being asked to participate in a research study to investigate the relationship of my work schedule, how I feel and my childbirth experience. I am being asked to participate in this study because I am a pregnant woman in the military.

A total of 380 women are expected to participate in this project of which 60 will be recruited from David Grant Medical Center, Travis Air Force Base.

Participation in the study will take about 60-75 minutes over a period of 1-5 months depending on the length of my pregnancy.

PROCEDURES

(This section will explain all procedures and the purpose of the procedures to be undergone as part of this study. Any experimental procedures will be explained as such)

If I agree to be in this study, the following will happen.

- At the prenatal clinic, I will be asked to complete questionnaires measuring how I feel, what my job is like, recent changes in my life, social and family support, my experiences with eating and sleeping at this time in my pregnant.
- 2 I will fill out a diary which will measure how I feel upon awakening, at midday and at bedtime for two consecutive work days and return it to the investigators in a stamped envelope.
- 3. The investigators will examine the hospital record of my baby's delivery to obtain information about the delivery
- 4. I will get a monthly telephone call from one of the investigators or research assistant who will ask me about job changes and them number of hours I worked per week during the month

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BENEFITS

I understand that no benefit can be guaranteed. However, the information I provide may help future working pregnant women in the prevention of preterm delivery.

(This section will explain your alternative treatment possibilities)

If I choose not to participate in this study, I will continue to receive all regular care.

RISKS/INCONVENIENCES (Any discomfort, risks, inconveniences caused from procedures or drugs used that may be expected from participation in this study.)

I may feel uncomfortable with some of the items on the questionnaires, two day diary or questions during the telephone call. If any of the questions in the questionnaire, diary or telephone calls make me uncomfortable, I can refuse to answer the question or stop the study at any time.

EVENT OF INJURY

I understand that my entitlement to medical and dental care and/or compensation in the event of injury is governed by federal laws and regulations, and if I have questions about my rights or if I believe I have received a research-related injury, I may contact the 60th Medical Group (DGMC) Patient Relations Monitor, at (707)423-3729, the Director of the Clinical Investigation Facility at (707)423-7400, and/or the investigator <u>CDR Janice Stinson</u> at (510) 769-8961.

OCCURRENCE OF UNANTICIPATED EVENT

If an unanticipated event (clinical or medical misadventure) occurs during my participation in this study, I will be informed If I am not competent at the time to understand the nature of the event, such information will be brought to the attention of my guardian or next of kin.

DECISION TO PARTICIPATE

The decision to participate in this study is completely voluntary on my part. No one has coerced or intimidated me into participating in this program. I am participating because I want to. My investigator(s) has adequately answered any and all questions I have about this study, my participation, and the procedures involved. I understand that the investigator will be available to answer any questions concerning procedures throughout this study. I understand that if significant new findings develop during the course of this study that may relate to my decision to continue participation. I will be informed. I further understand that I may withdraw this consent at any time and discontinue further participation in this study without prejudice to my entitlement to care. I also understand that the investigator of this study may terminate my participation in this study at any time if he/she feels this to be in my best interest. I have been provided a copy of this consent form

My signature below indicates my willingness to participate in this research study.

		·		
lubject's Printed Name)		(Subject's SSN)		
Subject's Signature)	() (FMP & Sponsor s	SSN)	(Date)	·

subject is a minor and in the opinion of the investigator(s) the minor can understand the nature and consequences of is/her participation in the study, the minor should be fully informed and indicate his or her assent by signing above. If uch minor subject is physically unable to sign, the parent or guardian may sign for him or her as evidence of the minor's issent.

Parent/Guardian's Signature)	(FMP" & Sponsor's SSN)	(Date)
(Advising Investigator's Signature)	(Investigator's SSN)	(Date)
(Witness's Signature)	(Witness's SSN)	(Date)

Distribution:

(1) Clinical Investigation Facility (60MDG/SGHC); [original]

(2) Research Volunteer. permanently);

(3) Volunteer's <u>Outpatient</u> Medical Record, (permanently maintained);

(4) Principal Investigator.

* FMP (Family Member Prefix) such as 20 - sponsor, 30 - pependent spouse, 01 - first child, etc.)

VOLUNTEER AGREEMENT AFFIDAVIT

PARTICIPATION INFORMATION: You have been invited to participate in a clinical investigational/research study conducted at Tripler Army Medical Center. It is very important that you read and understand the following general principles that apply to all participants in our studies, whether normal or patient volunteers: (a) your participation is entirely voluntary; (b) you may withdraw from participation in this study or any part of the study at any time; refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled; (c) after you read the explanation, please feel free to ask any questions that will allow you to clearly understand the nature of the study.

NATURE OF STUDY: The purpose of this project is to study the relationship of my work schedule, how I feel and my childbirth experience. To our knowledge, this study has never been done before with active duty military women.

EXPECTED DURATION OF SUBJECT'S PARTICIPATION: I understand my participation in this research project will be for a period of one to five months depending on the length of my pregnancy.

WHAT WILL BE DONE: If I agree to participate in this study, the procedure for this project involves the following:

1. At the prenatal clinic, I will be asked to complete questionnaires measuring how I feel, what my job is like, recent changes in my life, social and family suport, my experiences with eating and sleeping at this time in my pregnancy.

2. I will fill out a diary which will measure how I feel upon awakening, at midday and at bedtime for two consecutive work days and return it to the investigators in a stamped envelope

3. The investigators will examine the hospital record of my baby's delivery to obtain information about the delivery

4. I will get a monthly telephone call from one of the investigators or research assistant who will be ask me about job changes and the number of hours I worked per week during the month before the call.

REASONABLY FORESEEABLE RISKS OR DISCOMFORTS The risks or discomforts which are possible with this study are discomfort with wording on the questionnaires

BENEFIT(S) TO THE SUBJECT OR TO OTHERS: I understand that this research may not help me personally but that the results may help the investigators learn about determining the association of fatigueand occupational fatigue and preterm birth in active duty military women or aid in the treatment of other patients.

ALTERNATIVE PROCEDURES OR COURSES OF TREATMENT: If I choose not be in the study, I will continue to receive all regular care.

- CONFIDENTIALITY: Information gained because of my participation in this study may be publicized in the medical literature, discussed as an educational model, and used generally in the furtherance of medical science. Information from this study may be used as part of a scientific publication in medical or professional journals, but I will in no way be personally identified. Complete confidentiality cannot be promised to active-duty military personnel because information bearing on my health may be required to be reported to appropriate medical or command authorities.
- CIRCUMSTANCES UNDER WHICH YOUR PARTICIPATION MAY BE TERMINATED WITHOUT YOUR CONSENT: (a) Health conditions or other conditions that might occur which may be dangerous or detrimental to me or my health; (b) if military contingency requires it; (c) if I become ineligible for military care as authorized by Army regulation.

• ADDITIONAL COSTS TO SUBJECT THAT MAY RESULT FROM PARTICIPATION IN STUDY: Not applicable

- SIGNIFICANT NEW FINDINGS: Any significant new findings developed during the course of this study which could affect my willingness to continue participation will be made available to yme. The results of the research will be made available to me if I so desire. Complete results may not be known for several years.
- APPROXIMATE NUMBER OF SUBJECTS INVOLVED IN THE STUDY: A total of <u>380</u> subjects are expected to participate in this project of which 100 will be recruited from Tripler Army Medical Center.
- * DOMICILIARY CARE STATEMENT: The extent of medical care provided, should it become necessary, is limited and will be within the scope authorized for Department of Defense (DOD) health care beneficiaries. Necessary medical care does not include domiciliary (home or nursing home) care.

FOR FURTHER INFORMATION: Please contact the principal investigator, MAJ Nanette Liberatore, Obstetrical and Gynecology, (808) 433-5812, or the Associate investigator, CDR Janice Stinson, NC, USNR, (510) 769-8961. If I have any further questions about my rights, I may contact the Committee on Human Research, University of California, San Francisco between 0800 and 1700, Pacific Time, Monday through Friday by calling (415) 476-1814 or by writing, Committee on Human Research, Box 0962, University of California, San Francisco, CA 94143.

IF THERE IS ANY PORTION OF THIS EXPLANATION THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. A COPY OF THE VOLUNTEER AGREEMENT AFFIDAVIT WILL BE PROVIDED TO YOU.

I have read the above explanation and agree to participate in the investigational study described.

Typed Name & Signature of Volunteer

Date

Typed Name & Signature of Witness

Date

Appendix B

Research Assistant Training for Data Collection Instruments

RESEARCH ASSISTANT TRAINING RESEARCH PROJECT: ASSOCIATION OF FATIGUE AND PRETERM BIRTH IN ACTIVE DUTY MILITARY WOMEN PRINCIPAL INVESTIGATOR: CDR JANICE STINSON, NC, USNR

1. Each research assistant (RA) will be trained by the principal investigator, CDR Janice Stinson in a two hour training session.

2. The training session will consist of the following:

a. Each RA will be instructed in the overall purpose of the study: association of fatigue and preterm birth in active duty military women

b. Inclusion criteria will be reviewed with opportunities for questions:

1) 18 years and over (date of birth should also be used to calculate the age as women less than 18 should be excluded).

2) 22-26 weeks of gestation at time of enrollment and administration of the instruments. RAs will be instructed in use of estimated dates by last menstrual period, positive human chorionic gonadotropin (HCG) tests and the use of ultrasound corrective dating at 16-18 weeks to date the gestation.

3) singleton gestation. RA will instructed in where in chart to check for clarification of multiple gestation including ultrasound reports

4) no chronic illness or obstetrical problems. RAs will be shown how to check for chronic illnesses such as diabetes mellitus or cardiac problems and differentiate them from more acute problems such as broken bones, one time incidences of urinary infections. Obstetrical problems such as placenta previa, abruption, pregnancy induced hypertension as well as conditions that may affect the gestation such as history of cone biopsy, bicornate uterus, and DES intake by the subject's mother will be reviewed

5) No current treatment for vaginal or urinary tract infection. RAs will be instructed on where to find these diagnoses in the chart and clarification of when a treatment for such conditions may be considered complete

6) No history of preterm labor, preterm birth or spontaneous abortion. RAs will be instructed in definitions of preterm labor -- uterine contractions/cramps leading to cervical change, preterm birth - delivery before 37 weeks gestation and spontaneous abortion - termination of pregnancy before 20 weeks gestation not done intentionally either in or outside a clinical setting (eg. doctor's office or home)

7) No current treatment for preterm labor. RAs will be instructed in how a patient may be treated for preterm labor (diagnosis must be stated in chart)-- order of bedrest, medication with tocolytic such as terbutaline, nifedipine, ritodrine. AN ORDER OF DECREASED WORK HOURS ESP WITHOUT A DIAGNOSIS OF PRETERM LABOR WILL NOT BE CONSIDERED A TREATMENT FOR PRETERM LABOR IN THIS STUDY.

8) Intention to stay in military until delivery. Discussion of any possibility of discharge from active duty should be made

If the RA has any question about whether an active duty military woman should be included in the study, she should contact the principal investigator, CDR Stinson or the local point of contact.

c. The consent form will be reviewed in detail:

- 1) Purpose and background
- 2) Procedures survey tools, diary, examination of the inpatient chart, the phone calls

3) Risk/discomforts - The RAs will be instructed in the rights of the subject to drop out of the study at any time, importance of confidentiality and how to maintain confidentiality (identify subject by number except during phone calls; all data will be sent to the principal investigator for storage in a locked file)

4) Benefits - Discussion that although subjects will be paid for their participation, the information they provide will benefit future working pregnant women

5) Costs - Discussion of additional cost to subject other than her time to fill out instruments, fill out the diary and answer the phone calls

6) Reimbursement - Discussion of no reimbursement and why (cannot be paid twice via Federal funds)

7) Questions - Discussion of order of who subject needs to speak with if she has questions and the role of the University of California, San Francisco Committee on Human Research in this study

8) Consent - Discussion on verbal consent, voluntary nature of the study, importance that participation or no participation will not affect her status as a patient

d. Enrollment Procedure

1) The RAs will check with the prenatal clinic staff about the number of appointments of active duty military that day and when they are. The RA will talk with each pregnant active duty military woman who comes for her appointment, using the cover letter form. If the potential subject meets the criteria, the RA will notify the prenatal clinic staff and arrange for a half hour period of time to fill out the forms.

2) If the potential subject meets all criteria except that she is less than 22 weeks pregnant and she is willing to meet the RA later when she is between 22-26 weeks gestation, the RA will arrange to meet with the potential subject at that time. The RA will not look at the subject's chart until written consent for participation in the study is given.

e. Instrument packet will be reviewed. RAs will be instructed in checking the packet before each interview. Each form should have the subject's ID number of each page. The RA should ensure that the ID number on the pages correspond to the ID number on the outside of the packet. Each packet should contain:

- 1) Enrollment interview guidelines
 - a) enrollment interview checklist
 - b) Script: explanation of the research study
 - c) Prenatal chart review
 - d) Script: Explaining interview process
 - e) Script: Missing or ambiguous data
- 2) Script: POMS
- 3) POMS (1 page)
- 4) Script: VAS-F
- 5) VAS-F (2 pages)
- 6) Script: SDS
- 7) SDS (1 page)
- 8) Script: LEQ
- 9) LEQ (5 pages)
- 10) Script: OFI
- 11) OFI (1 page)
 - 12) Script: SBI
- 13) SBI (1 page)

14) Script: Demographic tools15) HHQ and D2 (4 pages)16) Script: Fatigue diary

17) Fatigue Diary (2 pages), stamped envelope

- 18) Telephone follow up (1 page)
- 19) Chart Review items (1 page)
- 20) Research Assistant reimbursement form

21) 2 pencils

f. RA will then fill out the tools: POMS, VAS-F, SDS, LEQ, OFI, SBI, HHQ and D2 as well as the fatigue diary. RA will then review two examples of charts of prenatal charts and two examples of delivered patients (permission will be obtained from medical records to do this confidentially).

g. The following issues will be discussed:

1) what to say to subjects if they asked clarification of an item on an instrument

2) how to dress for interview sessions, behaviors while subjects are filling out forms

3) how to point out missing or ambiguous data before the subject leaves the clinic

4) reiterate the importance of asking questions of the principal investigators if there are missing items in packets, questions of recruitment, trouble with following up on subjects

h. Plan of action for recruitment at the clinic. This needs to worked out between the RA and the clinic and may change depending on holidays, inservice days, etc. A suggested schedule is as follows:

1) Week 1: Mon-Wed-Fri - 0800-1200 2) Week 2: Tues-Thu - 1200-1600 3) Week 3: Mon-Wed-Fri - 1200-1600 4) Week 4: Tues-Thu - 0800-1200 ...or any combination of the above

The schedule will also depend on the number of active duty appointments scheduled, too. Bias caused by recruiting individuals who prefer afternoon appointments (eg. because they are fatigued in the morning or work night shift) needs to be avoided. Recruitment will continue every week for 4-5 months with a minimum of recruited (*range from 30 for Travis and 150 for San Diego*) for the study.

PREPARING FOR THE INTERVIEW

Please check your interview packet before each interview. Each form should have the subject's ID number on each page. Make sure that the ID number on the pages correspond to the ID number on the outside of the packet.

Each packet should contain the following:

- 1) Enrollment interview guidelines
 - a) enrollment interview checklist
 - b) Script: explanation of the research study
 - c) Prenatal chart review
 - d) Script: Explaining interview process
 - e) Script: Missing or ambiguous data
- 2) Script: POMS 3) POMS (1 page) 4) Script: VAS-F 5) VAS-F (2 pages) 6) Script: SDS 7) SDS (1 page) 8) Script: LEO 9) LEQ (6 pages) 10) Script: OFI 11) OFI (1 page) 12) Script: SBI 13) SBI (1 page) 14) Script: Demographic tools 15) HHQ and D2 (4 pages) 16) Script: Fatigue diary 17) Fatigue Diary (2 pages), stamped envelope 18) Telephone follow up (1 page) 19) Chart Review items (1 page) 20) Research Assistant reimbursement form 21) 2 pencils

If your packet is incomplete or the ID numbers are not correct, immediately notify CDR Janice Stinson (H) 510-769-8961, or local point of contact.

SCRIPT EXPLANATION OF THE RESEARCH STUDY

This research project is studying the association of differing energy levels of pregnant active duty women and their birth outcomes. Participants who meet the inclusion criteria to this study are consecutively selected in the prenatal clinic. All will be interviewed with survey instruments at recruitment between 22-26 weeks gestation and followed up with monthly phone calls until delivery. A chart review of the participants' inpatient delivery charts will be made to determine pregnancy outcome

Before we begin do you have any questions about the study?

PRENATAL CHART REVIEW

CLARIFYING INCLUSION CRITERIA

- 1. Maternal birth date _____ (Should be before January 1978)
- 2. Ultrasound Report at 16-18 weeks for gestational age

(Size should match gestational age at 16-18 week ultrasound)

3. Ultrasound Report at 16-18 weeks should indicate singleton

pregnancy _____

4. History in prenatal chart should indicate:

No chronic illnesses

No obstetrical complications for this pregnancy _____

No history of preterm labor, preterm birth or spontaneous_____

abortion if patient has had previous pregnancies _____

5. Progress note in prenatal chart should indicate:

No current treatment for vaginal infection _____

No current treatment for urinary tract infection _____

No current treatment for preterm labor _____

6. Intention to stay in the military until delivery ____

ASSOCIATION OF FATIGUE AND PRETERM BIRTH IN ACTIVE DUTY MILITARY WOMEN ENROLLMENT CHECKLIST

Dear Research Assistant,

This is an outline for the enrollment interview. Please follow this outcome and initial each component as you complete it. This will help ensure that all interviews are conducted in a similar manner.

_____1. Prior to the interview check your packets to make sure they contain all the materials needed for interview (see attached sheet. Notify CDR Stinson or local point of contact if any of your packets is incomplete. Make sure you have at 10 "Cover Letter for Voluntary Participation in a Clinical Investigation Study" forms and reimbursement forms

_____2. On the day of interview, confirm that a room is available for the interview before the first potential subjects arrive. Otherwise, plan to do the interview in the waiting room of the clinic.

____3. Check with the prenatal clinic staff for the active duty women who are scheduled for appointment. When these women arrive for their appointment, ask to speak to them and hand them the "Cover Letter for Voluntary Participation in a Clinical Investigation Study." Do prenatal chart review for the women willing to participate in study

____4. Notify the prenatal clinic staff of the women who agree to participate in the study and arrange to do the interview before or after their appointment.

___5. Explain the research study to the subject (see attached script) and verbal consent process

6. Explain the interview process to the subject (see attached script)

____7. Explain each tool and administer them in the order received

8. As each tool is completed, scan for missing or ambiguous marks. If there are missing or ambiguous data, have the subject complete the data or make corrections after all the questionnaires are completed (see attached script)

9. Make sure you remind the subject about sending the Fatigue Diary in the mail upon completion

10. To facilitate the telephone follow-up, plan approximate dates with the subject when the calls will take place to ensure she will not be out of town or unavailable at those times

11. Place the completed tools in the big packet (envelope). Seal envelope and initial that it is complete

12. If you have made an appointment in advance with subject (eg. those less than 22 weeks when you initially met them but met the criteria otherwise), please contact the subject and reschedule the appointment

13. Fill out reimbursement form weekly and return to CDR Stinson with packets.

Please return the completed packets to CDR Stinson within 1 week of the interview. Thank you

SCRIPT EXPLAINING INTERVIEW PROCESS

Before we start, let me tell you a little bit about the interview process since most people have not been in a study like this before.

This study is organized around content groups. These include things like your moods, energy levels, life changes, support, occupational factors and your health practices. All of these areas have been examined in other examined in other studies. Your answers will make it possible for us to learn more about the impact of what it is like to be a pregnant active duty women.

Use a pencil to mark your answers. If you want to change any answer, erase and make a new mark. Write as clearly as you can. As you complete each form, I will scan your answers to be sure they are legible for data entry.

SCRIPT

MISSING OR AMBIGUOUS DATA

In scanning, I noticed a few unclear items. We want to know exactly what you meant so your experience as a pregnant active duty member can be used to help other people in the future. Let's review these items to clarify what you intended.

When I turn these forms in, my supervisor will also scan them. Once in a while she may think we need clarification for an item and she or I may contact you

SCRIPT

POMS

This questionnaire is a list of words that describe feelings. It has been used in many studies and will give us information about how being pregnant in the military affects feelings as contrasted with how other conditions affect feelings. Please answer according to how you have been feeling this past week.

The range of the answers are from 0 to 4

POMS	4	234

Code ____

Below is a list of words that describe feelings people have. Please read each one carefully. Then fill in ONE circle under the answer to the right which best describes HOW YOU HAVE BEEN FEELING DURING THE PAST WEEK INCLUDING TODAY.

The numbers	
refer to these phrases.	

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- Not at all
- 🛈 = A little
- 0 = Moderately
- 🛈 = Quite a bit
- = Extremely

i Not at all A little Moderalety Quite a bit Extremely	Not at all A Inte Moderately Curite a bri	Not at all A little Moderatehy Quite a bit Extremely
1. Tense ⊙⊙⊙⊙⊙⊙	12. Uneasy	23. Weary @00000
2. Angry ⊙⊙⊙⊙⊙⊙	13. Fatigued	24. Bewildered OOOOO
3. Worn out ⊚⊙⊕⊙⊙⊙	14. Annoyed ⊙∩⊙⊙⊙	25. Furious @00000
4. Lively	15. Discouraged . OOOOO	26. Efficient ⊙⊙⊙⊙⊙⊙
5. Confused	16. Nervous	27. Full of pep ⊙⊙⊙⊙⊙⊙
6. Shaky ⊙⊙∂ЭЭ⊙	17. Loneiy	28. Bad-tempered 00000
7. Sad @CDDC	18. Muddied	29. Forgetful < <a>•
8. Active © 🖸 🖯 🛬	19. Exhausted	30. Vigorous ⊙⊙∂⊙⊙⊙
9. Grouchy ⊙⊡⊙⊙⊙⊙	20. Anxious · · DDDDC	
10. Energetic ⑥①②①①	21. Gloomy	MAKE SURE
11. Unworthy 🕠 ⓒⓒ고종 🗉	22. Siugg shere - @0000	EVERY ITEM.

PC PC

POMS CORYR GHT 1, 1989 Ed TS Educational and induction detection Service San Dinge, CA 92107 Reproduction of this formity any means strictly prohibited

SHORT FORM

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SCRIPT

VAS-F

This questionnaire is a visual analog scale with anchors representing two extremes of energy levels. Please place a mark similar to the example provided according to how you have been feeling right now.

VAS-F

Instructions

You are asked to place an "X" through these lines to indicated to indicate how you are feeling RIGHT NOW. For example, suppose you have not eaten since yesterday. Where would you put the "X" on the line below? not at all extremely hungry_____ hungry You would probably put the "X" closer to the "extremely hungry" end of the line. An example follows: not at all extremely hungry_____ V___ hungry ٨ NOW PLEASE COMPLETE THE FOLLOWING ITEMS: not at all extremely tired tired not at all extremely sleepy______sleepy not at all extremely drowsy_____ drowsy not at all extremely fatigued fatigued not at all extremely worn out worn out not at all extremely energetic energetic extremelv not at all active active not at all extremely vigorous______vigorous not at all extremely

not at all	extremely
lively	lively
not at all	extremely
bushed	bushed
not at all	extremely
exhausted	exhausted
keeping my	keeping my
eyes open	eyes open is
is no effort	a tremendous
at all	chore
moving my body is no effort at all	moving my body is a tremendous chore
concentrating is no effort at all	concentrating is a tremendous effort
carrying on	carrying on
a conversation	a conversation
is no effort	is a tremendous
at all	chore
I have	I have a
absolutely no	tremendous
desire to close	desire to
my eyes	close my eyes
I have	I have a
absolutely	tremendous
no desire to	desire to
lie down	lie down

SCRIPT

LEQ

This questionnaire includes events that could bring changes in the lives of those who experience them. Please note the events that occurred that occurred in your life during the last three months and circle: 1) whether they were good or bad and 2) how much the event affected your life -- from no effect to great effect.

If you have not experienced a particular event in the 1st three months, leave it blank. Please note there are 82

items on this questionnaire

LIFE EVENTS QUESTIONNAIRE

Instructions

Listed below are a number of events which may bring changes in the lives of those who experience them. Circle the events that have occurred in your life during the past 3 months and circle whether these were good or bad.

Show how much the event affected your life by circling the appropriate number which corresponds with the statement (0 = no effect, 1 = some effect, 2 = moderate effect and 3 = great effect).

If you have not experienced a particular event listed below in the past 3 months, LEAVE IT BLANK.

Please go through the entire list before you begin in order to get an idea of the types of events you will be asked to rate.

Event	Type of Effect		Effect of event on your life			r life
A. HEALTH			no effect	some effect	moderate effect	great effect
1. major personal illness or injury	Good	Bad	0	1	2	3
2. major change in eating habits	Good	Bad	0	1	2	3
3. major change in sleeping habits	Good	Bad	0	1	2	3
 major change in usual type and/or amount of recreation 	Good	Bad	0	1	2	3
5. major dental work	Good	Bad	0	1	2	3
6. (female): pregnancy	Good	Bad	0	1	2	3
7. (female): miscarriage or abortion	Good	Bad	0	1	2	3
8. (female): started menopause	Good	Bad	0	1	2	3
9. major difficulties with birth control pills or devices	Good	Bad	0	1	2	3
B. WORK						
10.difficulty finding a job	Good	Bad	0	1	2	3
11.beginning work outside home	Good	Bad	0	1	2	3

Event	Type of Effect	Ē	Effect of Event on Your Li			ır Life
B. WORK (cont.)			No effect	some effect	moderate effect	great effect
12.changing to a new type of work	Good	Bad	0	1	2	3
13. changing your work hours or conditions	Good	Bad	0	1	2	3
14. change in your responsibilities at work	Good	Bad	0	1	2	3
15. troubles at work with your employer or co-workers	Good	Bad	0	1	2	3
16. major business readjustment	Good	Bad	0	1	2	3
17. being fired or laid off from work	Good	Bad	0	1	2	3
18. retirement from work	Good	Bad	0	1	2	3
19. taking courses by mail or studying at home to help you in your work	Good	Bad	0	1	2	3
C. SCHOOL						
20. beginning or ceasing school, college, or training program	Good	Bad	0	1	2	3
21. change of school, college, or training program	Good	Bad	0	1	2	3
22. change in career goal or academic major	Good	Bad	0	1	2	3
23. problems in school, college, or training program	Good	Bad	0	1	2	3
D. RESIDENCE						
24. difficulty finding housing	Good	Bad	0	1	2	3
25. changing residence within the same town or city	Good	Bad	0	1	2	3
26. moving to a different town, city, state, or country	Good	Bad	0	1	2	3
27. major change in your living conditions (home improvements or decline in your home or neighborhood)	Good	Bad	0	1	2	3
E. LOVE AND MARRIAGE						
28. began a new, close, personal relationship	Good	Bad	0	1	2	3
29. became engaged	Good	Bad	0	1	2	3
30. girlfriend or boyfriend problems	Good	Bad	0	1	2	3

31. breaking up with a girlfriend or boyfriend or breaking an engagement	Good	Bad	0	1	2	3
32. (male): wife or girlfriend's pregnancy	Good	Bad	0	1	2	3
Event	Type of Effect	5	Effect	of Even	t on your	Life
E. LOVE AND MARRIAGE			No effect	some effect	moderate effect	great effect
<pre>33. (male): wife or girlfriend having a miscarriage or abortion</pre>	Good	Bad	0	1	2	3
34. getting married (or beginning to live with someone)	Good	Bad	0	1	2	3
35. a change in closeness with your partner	Good	Bad	0	1	2	3
36. infidelity	Good	Bad	0	1	2	3
37. trouble with in-laws	Good	Bad	0	1	2	3
38. separation from spouse or partner due to conflict	Good	Bad	0	1	2	3
39. separation from spouse or partner due to work, travel, etc.	Good	Bad	0	1	2	3
40. reconciliation with spouse or partner	Good	Bad	0	1	2	3
41. divorce	Good	Bad	0	1	2	3
42. change in your spouse or partner's work outside the home (beginning work, ceasing work, changing jobs, retirement, etc.)	Good	Bad	0	1	2	3
F. FAMILY AND CLOSE FRIENDS						
43. gain of a new family member (through birth, adoption, relative moving in, etc.)	Good	Bad	0	1	2	3
44. child or family member leaving home (due to marriage, to attend college, or for some other reason)	Good	Bad	0	1	2	3
45. major change in the health or behavior of a family member or close friend (illness, accidents, drug or disciplinary problems, etc.)	Good	Bad	0	1	2	3
46. death of spouse or partner	Good	Bad	0	1	2	3
47. death of a child	Good	Bad	0	1	2	3
48. death of family member or close friend	Good	Bad	0	1	2	3
49. birth of a grandchild	Good	Bad	0	1	2	3

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50. change in marital status of your	Good Bad	0	1	2	3
parents					

Event	Type of Effect		Effect	of Even	t on your	Life
G. PARENTING			No effect	some effect	moderate effect	great effect
51. change in child care arrangements	Good	Bad	0	1	2	3
52. conflicts with spouse or partner about parenting	Good	Bad	0	1	2	3
53. conflicts with child's grandparents (or other important person) about parenting	Good	Bad	0	1	2	3
54. taking on full responsibility for parenting as a single parent	Good	Bad	0	1	2	3
55. custody battles with former spouse or partner	Good	Bad	0	1	2	3
H. PERSONAL OR SOCIAL						
56. major personal achievement	Good	Bad	0	1	2	3
57. major decision regarding your immediate future	Good	Bad	0	1	2	3
58. change in your personal habits (your dress, life-style, hobbies, etc.)	Good	Bad	0	1	2	3
59. change in your religious beliefs	Good	Bad	0	1	2	3
60. change in your political beliefs	Good	Bad	0	1	2	3
61. loss or damage of personal property	Good	Bad	0	1	2	3
62. took a vacation	Good	Bad	0	1	2	3
63. took a trip other than a vacation	Good	Bad	0	1	2	3
64. change in family get-togethers	Good	Bad	о	1	2	3
65. change in your social activities (clubs, movies, visiting)	Good	Bad	о	1	2	3
66. made new friends	Good	Bad	о	1	2	3
67. broke up with a friend	Good	Bad	0	1	2	3
68. acquired or lost a pet	Good	Bad	0	1	2	3
I. FINANCIAL						
69. major change in finances (increased or decreased income)	Good	Bad	0	1	2	3
70. took on a moderate purchase such	Good	Bad	0	1	2	3

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as a T.V., car, freezer, etc.	
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Event	Type of Effect		Effect	of Event	on your	Life
			No effect	some effect	moderate effect	great effect
71. took on a major purchase or a mortgage loan, such as a home, business, property etc.	Good	Bad	0	1	2	3
72. experienced a foreclosure on a mortgage or loan	Good	Bad	0	1	2	3
73. credit rating difficulties	Good	Bad	0	1	2	3
J. CRIME AND LEGAL MATTERS						
74. being robbed	Good	Bad	о	1	2	3
75. being a victim of a violent act (rape, assault, etc.)	Good	Bad	0	1	2	3
76. involved in an accident	Good	Bad	0	1	2	3
77. involved in a law suit	Good	Bad	0	1	2	3
78. involved in a minor violation of the law (traffic tickets, disturbing the peace, etc.)	Good	Bad	0	1	2	3
79. legal troubles resulting your being arrested or held in jail	Good	Bad	0	1	2	3

I

K. OTHER

Other recent experiences which have had an impact on your life. List and rate

Event	Type of Effect		Effect	of Event	t on your	Life
			No effect	some effect	moderate effect	great effect
80	Good	Bad	0	1	2	3
81	Good	Bad	0	1	2	3
83	Good	Bad	0	1	2	3

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SCRIPT

SBI

This questionnaire measures the amount of support you get from two major groups: 1) members of your household (left column) and 2) people such as your friends or co-workers (right column). If you wish you can answer one column at a time

Note the range of answers is from 1 (dissatisfied) to 6 (very satisfied)...

Sh Copyrigi	orto nt -	ened • Mar	Vers ie A	ion nnet	of S te B	SBI rown						• .	
	н У d	How satisfied are you with the amount your partner/spouse does this for you?					Ho yo ot fo	ow sa ou wi chers elat or yo	tisf th t (fr ives) ou?	ied he a ienc do	are mour ls, thi	nt . s	
		Q				·	•	D				·	
	-DISSATISFIED	-SOMEWHAT DISSATISFIE	- PARTLY SATISFIED/ DADTLY DISSATISFIED	-SOMEWHAT SATISFIED	-SATISFIED	-VERY SATISFIED	-DISSATISFIED	-SOMEWHAT DISSATISFIE	-PARTLY SATISFIED/ PARTLY DISSATISFIED	-SOMEWHAT SATISFIED	-SATISFIED	-VERY SATISFIED	
ares similar experiences with	1	2	3	4		6	1	2	3	4	5	6	
lps keep up my morale	1	2	3	4	5	6	1	2	3	4	5	6	
lps me out when I'm in a pinch	1	2	3	4	5	6	1	2	3	4	5	6	
ows interest in my daily activities d problems	1	2	3	4	5	6	1	2	3	4	5	6	
es out of his/her way to do special thoughtful things for me	1	2	3	4	5	6	1	2	3	4	5	6	
lows me to talk about things that e very personal and private	1	2	3	4	5	6	1	2	3	4	5	6	
ts me know I am appreciated for things I do for them	1	2	3	4	5	6	1	2	3	4	5	6	
lerates my ups and downs and . usual behaviors	1	2	3	4	5	6	1	2	3	4	5	6	
kes me seriously when I have	1	2	3	4	5	6	1	2	3	4	5	6	
ys things that make my situation earer and easier to understand	1	2	3	4	5	6	1	2	3	4	5	6	
ts me know that he/she will be 'ound if I need assistance	1	2	3	4	5	6	1	2	3	4	5	6	

Code _____

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 $\sum_{i=1}^{n}$

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SCRIPT

SDS

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This questionnaire measures the amount of sleep you experienced in the past week.

Note the range of answer is from 0 (never) to 7 (every day)

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303	s	DS	
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Instructions

Please circle the degree to which you experienced the following symptoms in the past week.

		NEVER						EVEF DAY	<u>XY</u>
A.	have difficulty getting to sleep	0	1	2	3	4	5	6	7
в.	wake during your sleep period	0	1	2	3	4	5	6	7
c.	wake up too early at the end of a sleep period	0	1	2	3	4	5	6	7
D.	feel rested upon awakening at the end of a sleep period	0	1	2	3	4	5	6	7
Ε.	sleep poorly	0	1	2	3	4	5	6	7
F.	feel sleepy at work	0	1	2	3	4	5	6	7
G.	struggle to stay awake at work	0	1	2	3	4	5	6	7
н.	feel irritable at work	0	1	2	3	4	5	6	7
Ι.	feel tired or fatigued at work	0	1	2	3	4	5	6	7
J.	feel satisfied with the quality of your sleep	0	1	2	3	4	5	6	7
к.	feel alert and energetic at work	0	1	2	3	4	5	6	7
L.	get too much sleep	0	1	2	3	4	5	6	7
м.	get too little sleep	0	1	2	3	4	5	6	7
N.	nap at work during your scheduled breaks	0	1	2	3	4	5	6	7
о.	nap at work while actually on the job	0	1	2	3	4	5	6	7
Ρ.	drink an alcohol beverage to help you get to sleep	0	1	2	3	4	5	6	7
Q.	use tobacco to help you get to sleep	0	1	2	3	4	5	6	7
R.	use marijuana to help you get to sleep	0	1	2	3	4	5	6	7
s.	use an over the counter sleeping pill (Sominex, etc.) to help you get to sleep	0	1	2	3	4	5	6	7
т.	use a prescription sleeping pill to help you to get to sleep	0	1	2	3	4	5	6	7
U.	u se aspirin or other analgesic to help you get to sleep	0	1	2	3	4	5	6	7

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SCRIPT

OFI

This questionnaire lists the working conditions you may be experiencing. Please mark the right hand block with a check where applicable. Otherwise, leave the block blank.

OFI

Instructions

Please think about the working conditions you have been experiencing this past week and mark the right hand block where applicable.

Commute hours per week _____ How do you commute to work? _____

Occupational Source	Description	Check If Applicable
Posture	Posture in standing position more than three hours per day	
Work on industrial machine	Work on industrial conveyor belt, independent work on industrial machine with strenuous effort or vibrations	
Physical Exertion	Continuous or periodical physical effort; carry load of more than 20 lb.	
Mental Stress	Routine work; varied tasks requiring little attention without stimulation	
Environment	At least two of these elements: significant noise level, cold temperature or very wet atmosphere; manipulation of chemical substances	

5

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SCRIPT

DEMOGRAPHIC FORMS: HEALTH HABITS QUESTIONNAIRE AND DEMOGRAPHIC FORM

The following two questionnaires ask about your health habits in the past week including exercise, diet, beverages and smoking for the first one and items about your quarters, work conditions, education, income and ethnicity. Directions are self explanatory.

It's important that you leave a phone number so we can follow up on your work hours on a monthly basis.

1

HEALTH HABITS QUESTIONNAIRE

1. Please think about last week. How often did you:

		Days per Week	Minutes per day
a.	exercise strenuously (runs, walk briskly, bike, use an exercycle, swim, dance, etc.)		
b.	exercise moderately (floor exercises, work out, lift weights, isometrics)		
c.	eat 3 regular meals per day?	never0 rarely1 sometimes2 often3 always4	
d.	snack between meals?	never0 rarely1 sometimes2 often3 always4	
2.	How would you describe your appet	ite for the past week: excellent1 good2 fair3 poor4	
3.	Which of the following best descr light morni light morni large morni large morni other	ibes your meal please? ng, large evening1 ng, light evening2 ng, light evening3 ng, large evening4	L 2 3 1 5
4.	Is there anything unusual about y	our diet? No Yes	
	If yes, please explain		

5. Circle the number of serving of the following beverages you drank on an average day during the past week.

a.	coffee with caffeine0	1	2	3	4	5	6	7	8	9+
b.	coffee, decaffeinated0	1	2	3	4	5	6	7	8	9+
c.	tea with caffeine0	1	2	3	4	5	6	7	8	9+
d.	<pre>tea (herbal/decaffeine).0</pre>	1	2	3	4	5	6	7	8	9+
e.	soft drink (cola with caffeine0	1	2	3	4	5	6	7	8	9+
f.	milk0	1	2	3	4	5	6	7	8	9+
g.	wine0	1	2	3	4	5	6	7	8	9+
h.	beer0	1	2	3	4	5	6	7	8	9+

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HEALTH HABITS QUESTIONNAIRE (CONT'D)

i.	liquor0	1	2	3	4	5	6	7	8	9+
j.	liqueur or cordial0	1	2	3	4	5	6	7	8	9+

6. Which of the following best describes your cigarette smoking behavior?

- I have never smoked......0 I quit.....1 I am trying to quit.....2 I smoke occasionally.....3 I smoke less than I used to....4 I smoke more than I used to....5 I smoke the same as always.....6 If you do smoke, is it
- less than a pack a day.....1 about a pack a day.....2 more than a pack a day.....3

Y

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DEMOGRAPHIC QUESTIONNAIRE

Your age:	Your birthdate:	
Rate/Rank:	Duty Station:	
Years in Service:	Branch of Service:	
Marital status (Check on	e)	
Married		Divorced
<pre> Not married, livi with partner</pre>	ng	Separated
Never married		Widowed
People living with you (please do not give nam	es):
Relationship		Age (Years)
-		
· · · · · · · · · · · · · · · · · · ·		
Housing situation:		
Base Quarters	Civilian	Apartment Building
Ship	Civilian	Detached House
1. What is your present	occupation?	
2. Does your job involv	e working weekends?	Yes1 No2
3. Does your job involv	e working nights?	Yes1 No2
If yes, what hours?	to	
4. At the present time,	do you work at more t	han one job? Yes1 No2
5. How many hours a wee	k do you work?	hours
Are you satisfied wi	th your working situat	ion? Yes1 No2
If no, why not?		
DEMOGRAPHIC QUESTIONNAIRE (CONT'D)

6. On the average, how many hours each week, if any, do you now devote to the following activities?

Activity	Hours/Week
Homemaking (maintaining a home, housework)	
Student activities (going to class, studying)	
Volunteering, for example, professional or community activities	
parenting or child care	
leisure/recreation	
maintaining a close relationship with another adult eg. spouse or friend	
other (specify)	

7. Circle the highest grade of school that you completed:

0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 more

Family Income:

Please check the amount closest to your <u>FAMILY'S TOTAL INCOME</u> last year. Be sure to count money from all sources such as wages and salaries earned by all family members, help from relatives, stocks and so on.

Under \$3,000	\$25,000-29,999
\$3,500-4,999	\$30,000-34,999
\$5,000-6,999	\$35,000-39,999
\$7,000-9,999	\$40,000-49.999
\$10,000-14,999	\$50,000-59,999
\$15,000-19,999	\$60,000-69,999
\$20,000-24,999	\$70,000 or more

Ethnicity:

Check the correct ethnic group for which you belong:

 Asian		Native American Indian
 African-American		White
 Latino	<u> </u>	Other

PLEASE PROVIDE YOUR NAME AND A PHONE NUMBER YOU CAN BE REACHED ON A MONTHLY BASIS UNTIL YOU DELIVER. THIS INFORMATION WILL BE KEPT IN STRICT CONFIDENTIALITY. Name Phone () .

TWO DAY DIARY (PEARSON-BYARS FEELING TONE)

Instructions:

Please mark your energy level at these different times and briefly list how you might account for this energy level for TWO CONSECUTIVE WORK DAYS. Please return this form in the stamped envelope included with this form.

.

	1	2	3	4	5	6	7	8	9	A
xtremely eppy	 Very Fresh	Quite Fresh	Somewhat Tired	Little Tired	Little Pooped	Fairly Well Pooped	 Petered Out	Very Tired	Extremely Tired	Dead Tired
ecify	how you	account	for thi	s energy	/ level:					
			•							
DAY #1 (NOON OR	MIDWAT	сн) -		_		_	•	•	
U T	1 	2 	3	4	5	6 	7	8	9	A
 Extremely	i Very Fresh	 Quite Fresh	i Somewhat Tired	 Little Tired	Little Pooped	¦ Fairly Well Pooped	 Petered Out	 Very Tired	¦ Extremely Tired	¦ Dead Tired
Peppy										
Specify	pon Àon	accoun	t for thi	.s energ	y level:					
Specify	pom Xon	accoun	t for thi	s energ	y level:					
Specify DAY #1	how you	accoun	t for thi	s energ	y level:					
Specify DAY #1	how you (BEDTIME 1	accoun	t for thi	s energ	y level:	6	7	8	9	A

•

^	~	~		
	•	6		
1.				

Page 2

Code _____

TWO-DAY DIARY (CONT'D)

DAY #2 (UPON AWAKENING)

0	1	2	3	4	5	6	7	8	9	A
Extremely Peppy	Very Fresh	Quite So Presh	omewhat Tired	Little Tired	Little Pooped	Fairly Well Pooped	Petered Out	Very Ex Tired 7	tremely fired	Dead Tired

~

Specify how you account for this energy level:

DAY #2 (NOON OR MIDWATCH).

0	1	2	3	4	5	6	7	8	9	A	
Extremely Peppy	Very Presh	Quite Fresh	Somewhat Tired	Little Tired	Little Pooped	Fairly Well Pooped	Petered Out	Very Tired	Extremely Tired	Dead Tired	

Specify how you account for this energy level:

DAY #2 (BEDTIME)

0	1	2	3	4	5	6	7	8	9	A	
Extremely Peppy	Very Fresh	Quite Fresh	Somewhat Tired	 Little Tired	Little Pooped	Fairly Well Pooped	Petered Out	Very Tired	Extremely Tired	Dead Tired	

2

Specify how you account for this energy level:

Appendix C

Newsletter to Research Assistants

Research Assistant (RA) MEETING MINUTES "LESSONS LEARNED" NEWSLETTER "ASSOCIATION OF FATIGUE AND PRETERM BIRTH IN ACTIVE DUTY MILITARY WOMEN"

1. Recruitment

a. Clinic support is crucial to success in recruitment of subjects. One RA calls the clinic in advance to see if there are any active duty appointments (less than 26 weeks gestation) scheduled for the day before driving to the clinic. At 32nd St., the charge nurse of the clinic, Clinic staffencourage patients to participate. They also place a green X on research candidates' charts. At Coronado, a Nurse Practitioner also notifies one RA of potential candidates. Another RA does not receive as much individual support at Balboa but has free range of the clinic--asking pregnant women if they want to participate in whatever area they happen to be--from lab, to ultrasound to examination rooms

b. Both RAs have kept careful notes (a daily log of who they see) and track potential candidates as they progress through their pregnancy visits (prior to 22 weeks). If the patient has her 22-26 week appointment when either RA are not scheduled to be in the clinic, they call each other to see if the other can make it to the clinic for the interview

c. Part of waiting time at the clinic involves checking the appointment list for the next day either RA is in the clinic. In this way, they can plan coming to the clinic when that potential candidate's appointment happens to be. At 32nd St., one RA knows the schedule at least a week ahead of time. If there are no potential candidates, he simply does not come in.

d. At San Diego, the Glucose Tolerance Test (GTT) is scheduled at 22 weeks gestation. This is also a good time to conduct the interview as the patient has a long wait time between blood draws It would be helpful to find out if this test is done or some other time consuming test during the 22-26 week window at other research sites.

e. Be tenacious. One RA has been told that she looks like a "vulture" ready to pounce on the research subject as she leaves the exam room. This is sometimes necessary as, from their experience, both RA's have found pregnant women to be forgetful. During an appointment, it is essential not to allow the potential subject to "walk away."

f. Sometimes, subjects do not have the extra time to fill out questionnaires. Both RA's have arranged with their subjects to come back at a different time (not appointment day).

g. If the consent has not been signed and the secretary/nurse/MD at a site recognizes a potential candidate, the staff person, not the RA, should be the one who calls the potential research candidate.

2. Admin. Time

a. One RA, as the site project director, sets aside 1-2 hours of admin. time every Monday, organizing packets for mailing to the Principal Investigator (PI) and claims it on his time sheet

b. The other RA uses Tuesday morning as admin time to call subjects, remind them about the fatigue diaries and call them regarding their present work and working hours and claims this time on her time sheet

3. Conditions of taking questionnaires

a. At Balboa, free rooms are frequently not available. Therefore, questionnaires sometimes are filled out in the clinic

b. At 32nd St and Coronado, usually private rooms are available. This is preferable but not a requirement

4. Fatigue Diaries

a. The return rate has been about 70%. With telephone follow up, we can remind subjects to return their diaries. One RA has had a higher rate of return (over 90%) with his subjects

b. Suggest that the subject start the diary the day they fill out the questionnaire (providing it isn't Friday and they don't work the weekend) and complete it the next day and mail it immediately

c. The importance of filling out the fatigue diaries should be emphasized as the last thing to tell the subject before she leaves. One RA has had the challenge of seeing the subjects *before* they go for their check up; therefore, the importance of the fatigue diaries perhaps fades due to whatever is discussed during the check up. Suggestion: a call to subjects 1-2 weeks after the interview (as the first telephone follow-up and diary reminder) may be helpful

5. Comments regarding instrument

a. POMS, VAS, SDS, OFI - no problems

b. LEQ - emphasize that this is a generic questionnaires; format not straight; on page 1 regarding pregnancy, there should be some comment there

c. SBI - if subject is divorced, or if no partner; still may mark whether satisfied or not; This is not N/A

d. Health Habits Questionnaires -- mark all areas -- even if exercise is zero, do not leave it blank

e. Demographics - regarding parenting and maintaining relationship, mark amount of time when face-to-face with involved individual while awake; Income on 2nd column is reversed, but understandable

6. It may be better to recruit before 22 weeks so subjects can plan extra time in clinic (not apply to Balboa) esp. in quieter clinics where patients are seen with minimal waiting time

7. Eventually, you will start seeing your recruited patients who already filled out the questionnaires; make special effort to say "HI" to them so that they will be happy to remain in the study.

8. Master Roster, after 1 page is filled out, only need to photocopy the new pages that are being filled up.

Appendix D

Research Assistant Training for Chart Review

RESEARCH ASSISTANT TRAINING GUIDE CHART REVIEW PHASE "ASSOCIATION OF FATIGUE AND PRETERM BIRTH IN ACTIVE DUTY MILITARY WOMEN"

1. Welcome to the Chart Review Phase of "Association of Fatigue and Preterm Birth in Active Duty Military Women." Your training consists of two parts: (1) How to enter data in SPSS and (2) interpretation of 46 variables that need to be considered in this phase of data collection. Reliability training check list is attached. You will be looking at 6 charts. If your data entry matches 90% of my entries, you will have considered a reliable rater.

2. Remember, at any time during data collection, feel free to ask questions. If you are not sure how to enter in a variable, we all need to stop our data entry and discuss the issues involved and come to a decision. This will be added to the training guide such that the research assistants at all the other sites interpret variables the same way.

3. SPSS Data entry

a. Starting the Program

1. Turn on computer (purple button on left top of Compaq computer; button on left side of computer on Toshiba computer). Watch screen until you see DOS prompt (c:>)

1. Windows can be started by typing WIN after the DOS prompt on

Compaq

2. On Compaq computer only, the first program that loads is the *Program Manager* which provides you with a "desktop" that contains all of your Windows programs or applications

3. On both computers, start SPSS by moving the Mouse pointer to SPSS icon and double click button(press left side of top button on Compaq computer and press top button below keyboard on Toshiba computer) If you do not know how to use "mouse" let CDR Stinson know (basically you need to know how to click and drag the mouse; "click" means that you press the left mouse button and release when the pointer is on the area you want; "drag" means that you press the left mouse button, hold it down while moving the "mouse" -- gray ball below keyboard on Compaq and blue stick in middle of keyboard on Toshiba)

- b. Toolbar (see attached pages)
- c. Three "Windows" in SPSS Data, Output, Syntax.
 - 1. Four basic file extensions:

.sav indicates a data file in SPSS format .cht indicates a chart created with SPSS .sps indicates a syntax file .lst indicates an output file

2. For the most part, we will be working with Data window/format

d. Place Mouse pointer on File (above toolbar), select open and drag mouse to data. On data dialog box that appears, note files to left side of box and select file **chtsd.sav. Press OK**

e. On the Data Editor window that appears, the columns are the variables and the rows are the cases (each individual subject enrolled in the study) Note that the row number do not correspond to the case number. In statistical programs like SPSS, the subject's case number is a variable called **CODE**. This is a very important distinction to keep in mind.

1. Move around the cursor using the arrows to the bottom right of the keyboard of each computer. A border appears the cell indicating that it is an active cell.

2. The variable name and the row number are displayed in the upper right corner of the Data Editor window

3. The value that you type in is displayed above the row of variable names. When you press Enter, (or select another cell either with tab or an arrow), the value is entered into the cell. IF YOU MAKE A MISTAKE, DO NOT PRESS DELETE KEY TO ERASE A CELL, ESPECIALLY IF THERE IS DATA IN SUBSEQUENT ROWS. IF YOU DO THIS, THE VALUES OF SUBSEQUENT ROWS WILL SHIFT UP.

f. Modify/Replace values

1. Select the appropriate by the method in "e" above. Enter the new value. The new value replaces the old value in the cell editor. When you press enter or select a new cell, the new value appears in the cell

2. To modify a value, select the cell and click on the cell editor where the cell is displayed. Edit the cell. Press enter or select another cell and the new value will appear in the cell.

g. Format

1. Indicated in Code Book as eg. F3.2 or F5. The first number indicates the maximum number of places the value has before the decimal point. The second number after the decimal point, indicates the maximum number of places the value has after the decimal point.

2. If you need to change the format because a value does not fit the preplanned specifications, let CDR Stinson know

h. Value Label

1. Indicative of categorical variables. You can tell which value stand for which labels in a variable by:

a. Look at Code book

b. Press right side of Mouse button

2. If you need to add value labels as the patient eg. has a disease treatment not listed in preplanned specified treatments, let CDR Stinson know. We all need to discuss this because all the value labels need to match in the subsequent analysis

i. Saving the Data

1. Move mouse pointer to File, and drag mouse pointer to Save and click

2. Remember to save your data often (whenever you go to the bathroom, take a break, etc.) to avoid losing data

3. At the end of the day we will save data on hard disk to 3 1/2 inch disks, using the file manager which CDR Stinson will show you how to do. We will save data on at least two disks besides the hard disk at the end of each data collection day.

4. Interpretation of Variables

a. CODE = corresponds to four digit code number of subject. Check social security number, name and check on code number that corresponds.

b. GRAVIDA = number of pregnancies subject has had. Noted as "G" on front page of Standard Form 533

c. PARA= number of live births the subject has had with this baby. Noted as "P" on front page of Standard Form 533

d. EDC = Corrected due date based on fundal height/physician exam/ultrasound report

Format is form year, month, date

e. STARTPNC = Date started prenatal care (first provider exam)

f. NUMVIS = total number of prenatal visits

g. NOSHOWS = number of no show visits (large NS in block or date noted of appointment with no data -- possibly could be due to last minute cancellation of appointment--if this is so, please do not count; check prenatal chart progress notes for any indication that this is simply a missed visit)

h PRPREGWT= Pre-pregnant weight (in pounds)

i WTGAIN1= Weight gain/loss at the end of 12 weeks gestation

j. WTGAIN2= Weight gain/loss between 12 weeks gestation to at the end of 26 weeks gestation

k WTGAIN3= Weight gain/loss between 26 weeks gestation to the end of pregnancy

1. TOTWT=Total weight gain in pregnancy

m. HT=Height in inches

n HCT28WK= Hct at 28 weeks gestation (any hct after 25 weeks gestation to del)

o HGB28WK= Hgb at 28 weeks gestation (any hct after 25 weeks gestation to del)

p TXUTI= presence or absence of urinary tract infection in pregnancy

q UTIDATE=date of urinary tract infection; if more than one date, ask CDR Stinson to add variables

r. TXBV=presence or absence of bacteria vaginosis in pregnancy

s. BVDATE=date of bacteria vaginosis; if more than one date, ask CDR Stinson to add variables

t. TXSTD=note by value label -- sexually transmitted disease that occurred in pregnancy

u. STDDATE= date of sexually transmitted disease; if more than one date, ask CDR Stinson to add variables

v. TXOTHER=note by value label - other diseases occurring in pregnancy

w. OTHERDAT=date of other diseases occurring in pregnancy, if more than one date, ask CDR Stinson to add variables

x TXPTL=Treatment for preterm labor (labor contractions resulting in cervical change occurring before 37 weeks gestation)

y. PTLMED= Note by value label medication for preterm labor

z. PTLDATE=date of preterm labor; if more than one date, ask CDR Stinson to add variables

aa.CERVCHG= note by value label - amount of cervical change that occurred prior to treatment for preterm labor

bb TXPIH= presence or absence of pregnancy induced hypertension in pregnancy

cc PIHDATE=date of pregnancy induced hypertension diagnosis

dd. PIHMED=Note by value label- medication for pregnancy induced hypertension

ee. TXPROM=Presence or absence of premature rupture of membranes (membrane rupture before 37 weeks gestation)

ff. PROMDATE=date of premature rupture of membranes

gg. PNV= Taking of prenatal vitamins (indication in chart that patient was taking Prenatal vitamins -- more than likely in progress notes or on initial labor assessment)

hh FETCOMP=Note by value label-fetal complication during labor (see labor and delivery flow sheet); if you see other fetal complication like prolapsed cord, abnormal presentation, etc. see CDR Stinson regarding adding of variables)

Meconium - black tarry stool of infant before it is delivered

Fetal distress- fetal bradycardia -- <100 for longer than 30 seconds; late decelerations, severe variable decelerations -- where you note that the L&D nurse is treating the patient with oxygen, IV bolus, encouraging pt to lie further on her side or on hands and knees, turning off the pitocin

IUGR- intrauterine growth retardation

ii. DELDATE=Delivery Date of infant

jj. DELCOMP=Note by value label-delivery problems or lack of problems Normal vaginal delivery - SVD, vaginal delivery

Elective cesarean - usually a planned c-section ahead of time usually due to breech presentation

Cesarean section due to fetal distress (see above regarding definition of distress) Ceserean section due to CPD- cephalopelvic disproportionment

Cesarean section due to FTP - failure to progress in labor (eg arrest in cervical dilatation for several hours without progress)

Cesarean section due to failed induction - failure of pitocin induction/PG gel/cervidil to dilate cervix with subsequent delivery of fetus

Cesarean section due to infection -pt has high fever, fetal tachycardia, note antibiotics given

Forceps/vac ext - delivery with Simpsons, Piper forceps, Mity Vac, Silastic vacuum 3rd or 4th degree laceration - laceration through anal sphincter (see in doctor's progress note)

PIH-pregnancy induced hypertension (diagnosed intrapartum period)

kk TXPP= Note by value label - postpartum complications Hemorrhage - pass large clots, large enough bleed requiring Methergine, more Pitocin or Prostaglandin (Hemabate)

Nausea-vomiting- note that vomiting occurred, required medication such as Reglan, Droperidol

Chorioamnionitis- pt has fever, uterine tenderness, requiring antibiotics

Wound infection- from episiotomy, laceration, c-section wound problem--purulent drainage, hematoma

PIH - pregnancy induced hypertension (diagnosed in postpartum period)

II. REASPTB=note by value label- from progress note reason for preterm birth
 Elective-IUGR - elective induction due to growth retardation
 Elective-PIH - elective induction due to severe PIH
 Elective-infection/PROM - elective induction due to infection or ruptured membranes
 Spontaneous - due to urinary tract infection
 Spontaneous - Bacterial vaginosis
 Spontaneous - sexually transmitted disease

mm. INFWT =Infant's birthweight in grams

nn APGAR1= 1 minute Apgar

oo. APGAR5= 5 minute Apgar

rr. EDCAGE=Calculation of gestation age by dates at end of pregnancy

ss.USAGE=Ultrasound calculation of gestational age by end of pregnancy

tt. DUBOWITZ=Assessment (usually by nursery nurse) of infant gestational age by physical and neurophysio symptoms

uu. INFCOMP=Infant complications as noted by value lables

Hypothermia - temp consistently below 98 degrees Fahrenheit Poor feeding - noted in nursing notes - poor feeding, spitting up Jaundice requiring treatment - Bilirubin level taken, baby taken for bililight treatment in

nursery

Infection requiring treatment - High fever, or infection based on maternal temp, antibiotics given

Hypoglycemia - blood sugar below 40 - nursing note stating that infant given glucose water or formula to inc. blood sugar

vv. NICUSTA=number of days infant stayed in NICU

Appendix E

Explanation of Military Rank

In this study, women were recruited from the Army, Air Force, Coast Guard, Marine Corps, Navy and Public Health Service (PHS). Rank is a marker for higher socio-economic status in the military. All officers are expected to have at least a bachelor's degree; while some enlisted women may have more education than officers, this is not an expectation. In this study, officers averaged 16.9 years of school while enlisted averaged 12.5 years (t=22.541, p<.001) Officers also generally have higher incomes due to a Congressionally approved pay scale where officers earn roughly twice as much as enlisted. In this study, officers averaged in the \$50,000-59,999 range while enlisted averaged \$20,000-29,999 (t=11.483, p<.001). Although this was not measured in this study, officers, due to their rank, generally have a higher occupational status than enlisted. A total mood score (Profile of Mood States) comparison indicated that enlisted women had a higher mood score than officers (t=2.245, p=.025) although this scale may have reflected more on outlook on life rather than status on the job. Officer status may also be a marker for greater life stability (due to high standards as to what is "proper" behavior as conduct becoming of an officer) with 90% of the officers who were married in this study as opposed to only 58% of the enlisted (χ^2 = 13.592, p=.009). Enlisted spend their first 1-2 years as E-1 to E-3 and are given more pay and responsibility as E-4 and beyond. E-7's (usually after 10 years of service) are given special recognition, housing and clubs as senior enlisted. Officers spend their first 5 years as O-1 and O-2. Senior rank is considered O-4 and beyond which usually occurs after 10 years of service.

Appendix E - Continued

Explanation of Military Rank

For clarification regarding names of ranks for each of the respective services, the following chart of the ranks of women recruited in the study is provided:

Enlisted Ranks

<u>Ranks</u>	<u>Army</u>	Air Force	<u>Marines</u>	Navy/Coast Guard/PHS
E-1	Private (no insignia)	Airman Basic	Private (no insignia)	Seaman Recruit
E-2	Private	Airman	Private First Class	Seaman Apprentice
E-3	Private First Class	Airman First Class	Lance Corporal	Seaman
E-4	Corporal or Specialist	Sergeant or Senior Airman	Corporal	Petty Officer Third Class
E-5	Sergeant	Staff Sergeant	Sergeant	Petty Officer Second Class
E-6	Staff Sergeant	Technical Sergeant	Staff Sergeant	Petty Officer First Class
E-7	Sergeant First Class	Master or First Sergeant	Gunnery Sergeant	Chief Petty Officer
Officer	<u>*S</u>			
<u>Rank</u>	Army	Air Force	<u>Marines</u>	<u>Navy/Coast Guard/PHS</u>
O-1	Second Lieutenant	Second Lieutenant	Second Lieutenant	Ensign
O-2	First Lieutenant	First Lieutenant	First Lieutenant	Lieutenant Junior Grade
O-3	Captain	Captain	Captain	Lieutenant
O-4	Major	Major	Major	Lieutenant Commander
O-5	Lieutenant	Lieutenant Colone	Lieutenant el Colonel	Commander Colonel

Appendix F

Value of the Four Diagnostic Statistics $\Delta \chi^2$ (Chi Sq. Chg), ΔD^2 (Deviance) and h (Leverage), Observed Outcome (y), Estimated Outcome Probability (π), $\Delta\beta$ (Cook's) and data for variables for the Ten Most Extreme Subjects for Model Predicting Preterm Labor

Δχ2	ΔD^2	h	у	π	Δβ	Fatigue	Posture	Sleep	Officer	Neg LEQ
Nights	Caffe	ine L	ow Hgb							
36.12	7.31	.01	1	.03	.03	61	1	51	0	4
27.07	0 6.73	/ .009	1	10.6 .03	.26	79	0	52	0	8
	0	5		11.9						
18.41	6.02	.014	1	.05	.28	76	0	20	0	3
17.05	0 5.88	2 .015	1	11.8 .06	.27	124	0	66	0	10
	1	2		12.4						
16.46	5.80	.013	1	.07	.22	19	0	23	0	8
	0	4		11.1						
12.92	5.36 1	.017 3	1	.07 13.0	.23	78	0	78	0	11
12.45	5.30	.018	1	.08	.23	84	0	29	0	11
	0	2		12.0			•		•	
11.83	5.18	.014 2	1	.08	.17	65	0	58	0	6
11.05	5.08	.020	1	.09	.22	22	0	40	0	4
	1	8		12. 8						
10.2 8	4.97	.025	1	.09	.26	32	1	23	0	0
	1	3		11.7						

a y: 1= Preterm Outcome; Posture: 0=No; 1=Yes; Rank:0=enlisted; 1=officer; Night:0=No;1=Yes;Other variables: show actual numbers High $\Delta \chi^2$ and deviance is >4.0 and high leverage for this model is >0.1 (Hosmer-Lemeshow,

Figh $\Delta \chi^2$ and deviance is >4.0 and high leverage for this model is >0.1 (Hosmer-Lemesnow, 1989, p. 169)

The fitted model predicts an officer, with low fatigue, low sleep disturbance, low caffeine intake, work nights, low hemoglobin with a high negative life events score to go into preterm labor.

The subject with a $\Delta \chi^2$ of 36.12 is an enlisted woman who has average fatigue, has average sleep disturbance, does not work nights and high caffeine intake, has a hemoglobin above 10, and a low negative life event score (within 1 standard deviation) She fits the model in that she has a job with a posture risk factor. This pattern portrays poor fit but low leverage. The configuration of the covariates is biologically plausible

The subject with a $\Delta \chi^2$ of 27.07 is an enlisted woman with a high fatigue, average sleep disturbance, does not work nights, a high caffeine intake and a negative life events score that is lower than average (within 1 standard deviation). She fits the model in that she has low fatigue. Like the first subject, this pattern portrays poor fit but low leverage. The configuration of the covariates is biologically plausible

Appendix F - continued

Value of the Four Diagnostic Statistics $\Delta \chi^2$ (Chi Sq. Chg), ΔD^2 (Deviance) and h (Leverage), Observed Outcome (y), Estimated Outcome Probability (π), $\Delta\beta$ (Cook's) and data for variables for the Ten Most Extreme Subjects for Model Predicting Preterm Birth^a

$\Delta \chi^2$	ΔD^2	h	у	π	Δβ	Sleep	Marita	al Rank	People	Neg. LEQ
39.02	7.45	.009	1	.02	.37	19	0	0	2	0
19.67	6.11	.009	1	.04	.17	68	0	0	1	14
17.99	5.97	.014	1	.05	.25	58	1	0	2	6
17.20	5.9	.016	1	.05	.28	51	1	0	2	4
17.09	5.86	.012	1	.05	.21	34	1	0	4	4
16.85	5.83	.011	1	.06	.19	27	0	0	1	3
15.64	5.69	.011	1	.06	.18	19	0	0	1	4
14.51	5.59	.019	1	.06	.28	67	1	0	1	24
12.47	5.27	.012	1	.07	.15	39	1	0	1	0
12.20	5.49	.06	1	.07	.75	66	0	1	3	29

a y: 1= Preterm Outcome; Marital: 0=not married, 1=married; Rank: 0=enlisted, 1=officer; Other variables: show actual numbers

The fitted model predicts a married officer with low sleep disturbance, fewer people living in the household besides herself and have high negative life events to have a preterm birth

High $\Delta \chi^2$ and deviance is >4.0 and high leverage for this model is >0.1 (Hosmer-Lemeschow, 1989, p. 169)

The subject with $\Delta \chi^2$ of 39.02 is a single enlisted woman with, with more than 1 person in household beside herself and denies negative life events. She fits the model in that she has low sleep disturbance.

The subject with $\Delta \chi^2$ of 19.67 is a single enlisted woman with high sleep disturbance, and has higher than average negative life events. She fits the model in that she has fewer people living in household besides herself.

These are examples of poor fit and low leverage. But they are biologically plausible and should bekept in the model

Appendix G

Outlier Graph for Preterm Labor

Chi Square Change By Probability of Preterm Labor 40 30 20 10 CHG2X2 0 -10 .3 .2 .4 .5 .6 0.0 .1 .7 Predicted Value

Appendix H

Outlier Graph for Preterm Birth



Appendix I

Pregnancy Profiles and Instructions - United States Air Force, Army, Navy

Air Force Pregnancy Profile

- 1. Excused from immunizations which are contraindicated during pregnancy
- 2. Excused from aerobics testing and weight management program participation
- 3. Ionizing Radiation:

a. no occupational exposure to ionizing radiation without environmental assessment of exposure potential and clearance by OB-GYN profile physician

b. no exposure to diagnostic and therapeutic ionizing radiation without clearance by OB-GYN profile physician or Environmental Health consultant

4. No work over 12 hours a day, maximum 48 hours per week, maximum 6 duty days per week

5. No intentional exposure to tear gear. Must attend nuclear, biological and chemical (NBC) warfare training, but may not enter the chamber. Chemical warfare defense ensemble will e worn IAW AFR 160-12, C2

6. No lifting greater than 20 pounds elbow high

7. Remove from mobility position, if assigned

8. Will continue to wear duty uniform as long as it fits and meets military standards and image, then must wear maternity uniform

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For use of this form see Al	PHYSI		ne Office of Th	e Surne	on Geo	eral					
1. MEDICAL CONDITION		A CONTRACT AND A CONTRACTACT AND A CONTRACT AND A CONTRACT AND A CONTRACTACT AND A CONTRACTACTACTACTACTACTACTACTACTACTACTACTACTA		2.	0.000						
Pregnancy, estimated delivery dat	.e				Р Т-3	U 1	L 1	н 1	Е 1	s 1	
3. ASSIGNMENT LIMITATIONS ARE AS FOLLOWS								co	DES		
See attached sheet, items 1 throu	ugh 8.										
4. THIS PROFILE IS PERMANENT	TEMPORA	RY EXPIRATION DA	те 42 da	ays a	fter	de	liv	ery			
5. THE ABOVE STATED MEDICAL CONDITION SHOULD NOT	PREVENT THE		DOING THE	FOLLOW	ING A	CTIVIT h	IES	Nach		'n	
Hip Raise Quada Stretch & Bal	Single Kne	e to Chest		ack Stre	Ich		Ē	Ankl	e Stret	ch	
Knee Bender	Straight Le	g Raise	Chest St	retch			Ē] Hip :	Stretch		
Side-Straddle Hop Long Sit	Elongation	Stretch	One-Arm	Side St	retch		Ē		er Body	y Wt Ti	ng
High Jumper Hamstring Stretch	Turn and I	Bounce	Two-Arm	Side St	retch		Ē	Low	er Body	WITI	ng
Jogging in Place Hams. & Calf Stretch	Turn and I	Bend	Side Ber	nder			źĒ				•••
6. AEROBIC CONDITIONING EXERCISES	7. FUNCTIONAL	ACTIVITIES		8. TRA	NING	HEAR	T RAT	TE FOI	RMULA		
Walk at Own Pace and Distance	Wear Backo	ack (40 Lbs.)									
Run at Own Pace and Distance	Wear Heime	1				220		CC144	1 5 5 2	56	
Bicycle at Own Pace and Distance	Carry Rifle			M	ALES I	e e u		remA	163 27		
Swim at Own Pace and Distance	Fire Rifle				L		(-)	AGE			
Walk or Run in Pool at Own Pace	With Hea	ring Protection				AINUS	(-)	REST	ING H	EART P	RATE
	KP/Mopping	Mowing Grass			T	IMES	(x)	96 IN1	ENSIT	γ	
Unlimited Walking	Marching U	p to Miles			F	PLUS	(+)	REST	ING HI	EART I	RATE
Unlimited Running	Lift Up to 2	0 Pounds			_				_		
Unlimited Bicycling				5	- 0% EX	TREM	ELY	POOR	COND	ITION	
	<u> </u>			6	0% HE	ALTH	Y. SE	DENT	ARY IN		JAL
	PHYSICAL FITI	NESS TEST		7	0% MC	DERA	TEL		VE, M/		ANCE
Hun at Training Heart Rate for Min.		un 🛄 Walk		8	0% WE	ELL TP		D IND	IVIDUA		
Bicycle at Training Heart Rate for Min.	Push-Ups										
Swim at training rieart Hate for Min.	Sil-Ups					<u></u>					
Heart rate should not exceed 140)/minute.										
TTED NAME AND GRADE OF PROFILING OFFICER	SIGN	ATURE							DATE		
TYPED NAME AND GRADE OF PROFILING OFFICER	SIGN	ATURE						\rightarrow	DATE		
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	DUTY ASSIGN	MENT BECAU	SE:								
TYPED NAME AND GRADE OF UNIT COMMANDER	SIGN	ATURE							DATE		
PATIENTS IDENTIFICATION (For long of writing solition of	Alama liast for										
middle), grade, SSN, hospital or medical facility)	e marrie reişt, rifsi										
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DA FORM 3349, MAY 86 REPLACES DA FORM 5302-R (TEST) DATED FEB 84 AND DA FORM 3349 DATED 1 JUN 80. WHICH ARE OBSOLET TAME OP 36, DA FORM 3349, 1 May 92 (OB)

STANDARD PREGNANCY DUTY LIMITATIONS (AR 40-501, with revisions, May, 1990, HQDA)

The following are additional limitations regarding pregnant service members as outlined in AR 40-501. The intent of these provisions is to protect the fetus while ensuring productive utilization of the servicewoman. Common sense, good judgment, and cooperation must prevail between policy, patient, and patient's commander to ensure a viable program.

a. Except under unusual circumstances, the soldier should not be reassigned unless cleared by her physician to or from overseas commands until pregnancy is terminated. (See AR 614-30 for waiver provisions.)

b. Upon the diagnosis of pregnancy, the soldier is exempt from the regular prysical training (PT) program of the unit, exempt from physical fitness testing, exempt from wearing of load bearing equipment, including web belt, exempt from all immunizations except influenza and tetanus-diptheria, and exempt from exposure to chemical agents in nuclear, biological, chemical (NBC) training. This includes wearing MOPP gear at any time for training purposes.

c. At 20 weeks of pregnancy, the soldier is exempt from standing at parade rest or attention for longer than 15 minutes. Exempt from participating in weapons training, swimming qualifications, drawn proofing, and field duty.

d. No assignment to duties where nausea, easy fatigability, or sudden lightheadedness would be hazardous to the soldier or others, to include all aviation duty, classes 1, 1A, 2 and 3. Class 2A, ATC personnel, may continue ATC duties with approval of the flight surgeon, obstetrician, and ATC supervisor.

e. May work stifts.

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f. At 28 weeks of pregnancy, the soldier must be provided a 15-minute rest period every 2 hours. Her workweek should not exceed 40 hours; however it does not preclude assignment as charge of quarters (CQ) and other like duties performed in a unit, to include normal housekeeping duties. (CQ is part of the 40-hour workweek.)

g. A woman who is experiencing a normal pregnancy may continue to perform military duty until delivery.

h. Convalescent leave after delivery will be for a period determined by an attending physician, normally 42 days. After completion of convalescent leave, soldiers are required to meet the standards of AF 350-15 (Army Physical Fitness Program) and AR 600-9 (Army Weight Control Program).

DEPARTMENT OF THE NAVY NAVRESREDCOM REG 22 Office of the Secretary MASTER CORALington DC 20350-1000 DO NOT REMOVE FROM FILES

SECNAV INSTRUCTION 1000.10

From: Secretary of the Navy To: All Ships and Stations

- DEPARTMENT OF THE NAVY Subj: (DON) POLICY ON PREGNANCY
- Ref: (a) DOD 4165.63-M of SEP 93 (DOD HOUSING MANAGEMENT MANUAL) (NOTAL) (b) U.S. Code, Title 10

1. Purpose

a. To provide a DON policy for all military personnel on pregnancy and issues related to pregnant servicewomen that will build positively on existing programs in the Navy and Marine Corps to ensure equality of opportunity while maintaining operational readiness;

b. To expand the requirements for education and training;

c. To establish a requirement for the collection of objective data, and analysis of information for use in evaluation of DON pregnancy policies;

d. To help guide the department's future efforts in this area.

2. Applicability. This instruction applies to all DON military personnel, both Regular and Reserve, except midshipmen.

3. Background

a. The mission of the DON requires the highest level of operational readiness to meet the nation's strategic goals. A full complement of highly trained personnel is essential to maintaining operational readiness in deployable units.

ASN(M&RA)

6 February 1995

SECNAVINST 1000.TO

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the Navy-Marine Corps Team. DON leadership recognizes that pregnancy is a natural event that can occur in the lives of Navy and Marine Corps servicewomen, and is not a presumption of medical incapability. Pregnancy could affect a command's operational readiness by temporarily limiting a servicewoman's ability and availability to perform all assigned tasks. Consideration of this reality requires establishment of policies and procedures which accord due regard to the demands of parenting in the Service and address career and health issues.

4. Policy. It is DON policy that:

naval service.

a. Pregnancy and parenthood are compatible with a naval career. The DON will ensure the health care needs of pregnant servicewomen are met and will accommodate the career and welfare NAVRESREDCUM needs of pregnant servicewomen to the greatest extent possible, consistent with the needs of the

00A b. Military responsibilities, including the 00A1 expeditionary nature of our Navy and Marine 00C 01 Corps, often add factors for serious considera-01A tion for our servicemen and servicewomen. 03 Appropriate and thorough family planning info 31 mation will be made available to our servicemen 32 and servicewomen throughout our training establ 33 lishment and at the unit level. Our goal is to <u>34</u> 35 ensure all personnel are aware of the broad range of medical, legal, financial, chaplain and other **4**2 51 services available to assist and encourage our and women in making family planning decision 06 07 that are supportive of both their naval service their parental responsibilities. 08

c. Advice concerning personal decisions, including issues of faith, character, parental responsibilities, individual core values and medical concerns, will be readily available to those who seek il.



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d. Services will provide detailed guidance for the assignment and management of pregnant servicewomen.

e. A servicewoman who is transferred from her unit because of pregnancy will be returned to the same billet, or an equivalent billet in a command of the same type duty, whenever possible to the same command, following her pregnancy and any related convalescent leave and period of deferment.

f. A servicewoman who suspects she is pregnant is responsible for promptly confirming her pregnancy through testing by an appropriate medical provider and informing her commanding officer of confirmation.

g. Regarding the requirement for appropriate housing for pregnant servicewomen, a pregnant active duty servicewoman with no family members may reside in Bachelor Quarters for her full term. If the servicewoman requests, the host commander may authorize a pregnant servicewoman to occupy off-base housing and be paid a basic allowance for quarters (BAQ) up to her twentieth week of pregnancy. From the twentieth week forward, the host commander must aprove such a request. Reference (a) outlines the policy for application to government family housing. Payment of BAQ will be in accordance with applicable pay and entitlement regulations.

h. Active duty servicewomen will be given priority in receiving routine obstetric/gynecologic (OB/GYN) care in all DON medical facilities.
Further, it is DON policy that active duty servicewomen assigned to imminently deploying units or positions (within 3 months) will be given priority over other active duty servicewomen
receiving routine OB/GYN care in all DON medical facilities. Under Chapter 55 of reference (b), active duty servicemembers have a statutory entitlement to care in medical facilities of the uniformed services. Such care is authorized for other categories of beneficiaries on a space available basis.

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i. Medical limitations and/or assignment restrictions, or periods of absence because of pregnancy or associated medical care shall not be the basis for downgrading marks or adverse comments. As always, evaluations and fitness reports shall be based on demonstrated performance.

j. A pregnant servicewoman may request separation from active duty. Requests for separation will not normally be approved unless there are extenuating circumstances or the request otherwise complies with criteria for separation promulgated by the Services.

k. The chain of command shall ensure that servicemembers will be afforded the opportunity to take advantage of available legal assistance for advice regarding their options in establishing paternity.

5. Action. The Chief of Naval Operations (CNO) and Commandant of the Marine Corps (CMC) shall:

a. Implement policies of this instruction no later than 60 days from date of signature.

b. Notify the Assistant Secretary of the Navy (Manpower and Reserve Affairs) of substantive changes to Service policies not less than 30 days prior to implementation of those changes.

c. Provide appropriate training as necessary to ensure consistency with the goals of paragraph 4b.

d. Ensure command support for all servicewomen to obtain OB/GYN care while on active duty. Reinforce current policy to ensure active duty servicewomen are afforded priority for routine OB/GYN care consistent with paragraph 4h.

e. Within 1 year of the issuance of this instruction and biennially thereafter, provide a report to ASN(M&RA) on the following:

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(1) Service analyses concerning the effect of pregnancy and other medical, administrative, and disciplinary factors on deployability of servicewomen and servicemen.

(2) Assessment of health care risks associated with pregnancy and other types of medical conditions that may exist for servicewomen and servicemen assigned to operational/deployable commands and support commands with significant occupational health considerations (e.g., ship and airplane construction/repair facilities, etc).

(3) Assessment of the training provided to officers and enlisted personnel to achieve the goals of paragraph 4b.

(4) Assessment of the impact of the policy and actions ensuring priority for routine OB/GYN care for active duty servicewomen and, within that category, first priority for servicewomen assigned to imminently deploying units or positions.

(5) Assessment of the worldwide availability of and access to appropriately staffed and equipped military OB/GYN medical support. This assessment should include the possible impact of mobilization and assignment of pregnant reserve servicemembers to stations within the continental U.S.

6. Report. The reporting requirement contained in this instruction is assigned Report Control Symbol SECNAV 1000-1 and is approved for 3 years from the date of this instruction.

JOHN H. DALTON Secretary of the Navy

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SECNAV/OPNAV Directives Control Office Washington Navy Yard Building 200 901 M Street SE Washington DC 20374-5074 (30 copies)

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Appendix J

<u></u>	<u>Sub</u>	scales	Total	Scale
Instrument/Subscale	# Items	Reliability	# Items	Reliability
Profile of Mood State	es			
	30	.89		
Anger	5	.87		
Confusion	5	.61		
Depression	5	.80		
Fatigue	5	.87		
Tension	5	.76		
Vigor	5	.86		
Visual Analog Scale			18	.86
Fatigue	13	.93		
Energy	5	.91		
Support Behavior Ind	lex		22	.92
Partner	11	.97		
Friends	11	.95		
Sleep Disturbance Inc	dex		21	.80

Internal Consistency Reliabilities (Cronbach Alpha Coefficients) (n= 359)

Note: Raw item alphas were used

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Concurrent Validity of Fatigue Scales (n=359)

	VAS-F	VAS-E	POM-F	V-MO4	DIA	DIM	DIP	D2A	D2M	D2P
VAS-F		395**	.628**	347**	.24**	.23**	.23**	.26**	.19**	.22**
VAS-E			303**	.587**	18*	26**	17*	2**	18**	.16**
POM-F				321**	.18*	.17**	.24**	.21**	.17*	.2*
POM-V					1	-23*	16*	13	14*	09
DIA						.29*	.23*	.55**	.26*	.195*
DIM							.29**	.24**	.57**	.27*
DIP								.24**	.32**	**9.
D2A									.47**	.31**
D2M										.39**
VAS-F = Vi POM-V=Pro D2A=Diary * - p=.01 *	isual Analog So ofile of Mood Day 2 Mornin * - p=.001	cale Fatigue; V State-Vigor; D1 g; D2M=Diary	AS-E= Visual . A=Diary Day Day 2 Midday	Analog Scale 1 Morning; D1 , D2P= Diary	Energy; P(M=Diary Day 2 Eve	OM-F=P Day 1 N ning	rofile o Aidday;	f Mood D1P=I	States- Diary 1	Fatigue; Evening;

Appendix L

Item	Variable	Factor 1	Factor 2
1.	Exhaust	.876	.117
2.	Tired	.859	.184
3.	Worn Out	.858	.196
4.	Sleepy	.855	.164
5.	Fatigue	.852	.192
6.	Drowsy	.807	.187
7.	Lie Down	.785	.152
8.	Close Eye	.781	.141
9.	Cannot Keep Eyes Open	.771	.245
10.	Bushed	.757	.228
11.	Cannot Move Body	.680	.133
12.	Cannot Concentrate	.607	.185
13.	Cannot Do Conversation	.475	.118
14.	Vigor	428	.748
15.	Energetic	521	.724
16.	Active	526	.705
17.	Lively	586	.674
18.	Efficient	409	.664
Variar Propo	nce rtion of Variance Accounted For	8.030 44.61%	3.892 21.62%

Factor Analysis of the Visual Analog Scale - Varimax Rotation Loadings of 18 Items

Appendix M

Variable	Group 1	Group 2	Group 3	Group 4	F or	p-value
	Travis Air Force (N=60)	Tripler Army (N=58)	San Dicgo Navy (N=152)	Portsmouth Navy (N-89)	χ²	
Age	25.52ª	24.09	22.91	24.51	5.06	0.002
Education	13.65 ^b	13.05	12.7	12.7	5.88	0.001
Rank	5.52°	4.50	3.79	4.19	6.40	0.001
Non-White	17 (28.8%)	21(36.2%)	60(39.5%)	38(42.7%)	3.17	0.367
Fatigue (Visual Anale	578.7 og Scale)	547.1	565.5	609.7	0.69	0.558
Energy (Visual Analo	207.3 og Scale)	178.5	182.7	207.8	2.13	0.097
Preterm Labo	or 8 (13.3%)	3 (5.2%)	22 (14.5%)	17 (19.1%)	5.75	0.124
Preterm Birth	n 5 (8.3%)	2 (3.4%)	18 (11.8%)	9 (10.1%)	358	0.310

Comparison of Site Categories on Mean Values and Counts (Percent of Group) of Demographic and Health Characteristics Using One-Way Analyses of Variance and Chi Square (n=359)

Note. All post-hoc comparisons were made using the Scheffe' method

^aGroup 1 is significantly higher than Group 3 at $p \le .05$. ^bGroup 1 is significantly higher than Groups 3 and 4 at $p \le .05$. ^cGroup 1 is significantly higher than Groups3 and 4 at $p \le .05$

Appendix M continued

Comparison of Military Branch Categories on Mean Values and Counts (Percent of Group) of Demographic and Health Characteristics Using One-Way Analyses of Variance and Chi Square (n=359)

Variable	Group 1 Air Force (n= 55)	Group 2 Army (n=30)	Group 3 Navy (n=258)	Group 4 Other (n=15)	F or χ^2	p-value
Age	25.00	24.43	23.58	25.07	1.76	0.154
Education	13.53ª	13.07	12.72	13.8	5.73	0.001
Rank	5.29 ^b	4.57	3.99	5.27	4.53	0.004
Non-White	16 (29.6%)	18(60.0%)	97(37.5%)	5 (33.3)	7.94	0.047
Fatigue (Visual Analo	582.0 g Scale)	575.0	579.0	495.0	0.43	0.732
Energy (Visual Analo	191.0 g Scale)	198.0	192.0	192.0	0.04	0.988
Preterm Labor	r 8 (14.5%)	4 (13.3%)	37 (14.3%)	1 (6.7%)	0.71	0.870
Preterm Birth	5 (9.1%)	1 (3.3%)	27 (10.4%)	1 (6.7%)	1.74	0.628

Note. All post-hoc comparisons were made using the Scheffe' method

^aGroup 1 is significantly greater than Group 3 at $p \le .05$ ^bGroup 1 is significantly greater than Group 3 at $p \le .05$

Appendix M continued

Comparison of Military Occupational Specialty Categories on Mean Values and Counts (Percent of Group) of Demographic and Health Characteristics Using One-Way Analyses of Variance and Chi Square (n=359)

Variable	Group 1 Moderate Stress (Clerical) (n=229)	Group 2 Mental Stress (Require Concentration) (n=18)	Group 3 Exposure to Hazardous Materials (n=31)	Group 4 Physical Stress (Active) (n=78)	\mathbf{F} or χ^2	p-value
Age	23.81	23.61	24.42	24.16	0.24	.868
Education	12.77	12.76	12.87	13.44ª	3.94	.011
Rank	4.14	3.83	4.10	4.91	1.93	.125
Non-White	86(37.4)	5(27.8)	13(43.3)	32(40.0)	17.50	.721
Fatigue (Visual Analo)	580.5 g Scale)	530.4	583.1	569.3	0.19	.900
Energy (Visual Analo)	19.70 g Scale)	14.22	18.00	21.28	2.54	.056
Preterm Labor	29(12.6)	3(16.7)	13(16.3)	13(16.3)	0.93	.818
Preterm Birth	18(7.8)	3(16.7)	5(16.1)	8(10.0)	3.44	.328

Note. All post-hoc comparisons were made using the Scheffe' method ^aGroup 4 is significantly higher than Group 1 at $p \le .05$.

•	2	5	
-	VIDUAL		•
•	4		•

and Environmental Demands (n=359) **Dotions** a Vianal Analae Caala o Dote 104 0 Degreen Product M

			Interna	l Environm	ental Demar	spi	
Depression	Anxiety	Sleep Disturbance	Age Hema 28 W	ttocrit H eeks 28	emoglobin } Weeks	Body Mass In 2 nd Trimester	lex
.37**	.33**	.57**	04313	Ţ	16*	011	
Caffeine .12	Moderate Exercise 078	Strenuous Exercise 057					
			Externa	l Environm	ental Demai	spu	
Social Support	Partner Support	Friend Support	Number Household	Work Hr Per Week	Occup Fatigu	ational e Index	Role Demand
11	12	036	.038	.038	080.		156*
Night/Duty Hours	Income	School in Years	Posit Life Changes	ive No Life Char	egative Iges		
.035	057	038	016	.29**			
Note: *p<.0	1 **p<.001						

Appendix O

T-tests Between Visual Analog Scale-Fatigue^a and Categorical Environmental Demands (n=359)

	Internal Env	vironmental Der	mands	
	Mean	<u>SD</u>	<u>Sample</u> Range	<u>T-Test</u>
Tobacco Use				
No exposure	554.5	290.4	0 - 1240	-1.739
Exposure	607.4	270.6	90 - 1230	(p=.083)
Alcohol Use				_
No exposure	572.2	248.7	0 - 1240	1.160
Exposure	661.8	284.5	190 - 1030	(p=.247)
Prenatal Vitamins				
No exposure	558.1	258.1	10 - 1240	367
Exposure	576.4	286.1	0 - 960	(p=.714)
	External En	vironmental De	mands	
Marital Status				
Married	577.9	265.0	0 - 1240	.183
Not Married	572.3	311.0	30 - 1230	(p=.855)
Housing				
Military	536.0	302.0	0 - 1240	1.802
Civilian	593.9	273.0	50 - 1230	(p=.072)
Role Demands				
Homemaking				
Yes	574.6	281.8	30 - 1240	.254
No	589.3	308.8	0 - 1230	(p=.800)
Student				
Yes	521.1	270.2	10 - 1110	2.201
No	595.3	286.0	0 - 1240	(p=.028)
Volunteering				
Yes	518.1	290.7	30 - 1000	1.642
No	586.1	281.3	0 - 1240	(p=.101)
Parenting				
Yes	545.1	297.2	10 - 1200	1.376
No	589.8	275.59	0 - 1240	(p=.170)
Leisure Activity				
Yes	572.5	276.8	0 - 1200	.514
No	594.4	322.3	60 - 1110	(p=.608)
Adult Relations				
Yes	566.6	286.5	0 - 1240	1.633
No	637.2	262.5	30 - 1060	(p=.103)
				- '

Appendix O - continued

T-tests Between Visual	Analog Scale-H	Fatigue ^a and Ca $(n-350)$	tegorical Environme	ental Demands
F	vternal Environ	(II-339) mental Deman	is continued	
L	<u>Mean</u>	<u>SD</u>	<u>Sample</u> <u>Range</u>	<u>T-Test</u>
People in Household (in	addition to resp	ondent)		
0-1	578.3	279.0	0 - 1240	264
≥2	569.7	294.0	10 - 1200	(p=.792)
Presence of Children <5	years old			
Yes	555.2	295.0	10 - 1130	.798
No	582.7	279.0	0 - 1240	(p=.426)
Military Occupational S	pecialty			
Clerical Jobs	580.5	276.0	0 - 1240	426
Other Jobs	567.2	298.0	10 - 1230	(p=.670)
Occupational Fatigue				
0-1	597.8	291.0	10 - 1230	996
≥2	565.7	280.0	0 - 1240	(p=.320)
Works on Weekends				
Yes	598.9	275.0	30 - 1240	1.473
No	554.8	290.0	0 - 1230	(p=.142)
Works at Night				
Yes	600.9	268.0	30 - 1240	1.279
No	561.2	291.0	0 - 1230	(p=.202)
Satisfaction with Work	Situation			
Yes	626.6	285.0	0 - 1240	2.383
No	551.1	280.0	10 - 1140	(p=.018)
Rank				
Officer	552.7	284.0	160 - 1140	472
Enlisted	577.9	284.0	0 - 1240	(p=.637)
Ethnicity				
White	573.5	274.0	30 - 1240	230
Non-white	580.6	299.0	0 - 1140	(p=.818)

^aVisual Analog Scale-Fatigue Instrument Range - 0 - 1300

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Pearson Product Moment Correlations Between Profile of Mood States-Fatigue and Environmental Demands (n=359)

			Interna	l Environm	ental Deman	ds	
Depression	Anxiety	Sleep Disturbance	Age Hema 28 W	ttocrit H eeks 21	emoglobin 8 Weeks	Body Mass Index 2 nd Trimester	
77.	.51	.52**	023039	Ļ	.085	.058	
Caffeine	Moderate	Strenuous					
.13	Exercise 017	exercise 050					
			Externa	l Environm	ental Demar	spu	
Social Support	Partner Support	Friend Support	Number in Household	Work Hr Per Week	Occup Index	ational Fatigue	Role Demand
083	047	-079	.043	.045	.17*		037
Night/Duty Hours	Income	School in Years	Posit Life Changes	ive N i Life Chai	egative Iges		
.029	006	.042	.030	.319**			
Note: *p<.0]							

**p<.001
Appendix Q

	Internal Env	vironmental De	emands	
	Mean	<u>SD</u>	<u>Sample</u> <u>Range</u>	<u>T-Test</u>
Tobacco Use				
No exposure	9.10	4.62	0 - 20	-2.212
Exposure	10.22	4.87	1 - 20	(p=.028)
Alcohol Use				
No exposure	9.50	4.73	0 - 20	880
Exposure	10.64	5.21	4 - 19	(p=.38)
Prenatal Vitamins				
No exposure	10.42	3.58	3 - 17	1.129
Exposure	9.48	4.82	0 - 20	(p=.260)
	External En	vironmental D	emands	
Marital Status				
Married	9.75	4.63	0 - 20	1.022
Not Married	9.23	4.9	0 - 20	(p=.307)
Housing				
Military	9.76	4.6	0 - 20	574
Civilian	9.45	4.8	0 - 20	(p=.566)
Role Demands				
Homemaking				
Yes	9.61	4.75	0 - 20	912
No	8.73	4.7	0 - 17	(p=.362)
Student				
Yes	8.95	4.92	0 - 19	1.442
No	9.77	4.67	0 - 20	(p=.150)
Volunteering				
Yes	9.13	4.96	0 - 17	.715
No	9.63	4.71	0 - 20	(p=.475)
Parenting				
Yes	9.45	4.73	0 - 20	.246
No	9.58	4.75	0 - 20	(p=.806)
Leisure Activity				
Yes	9.68	4.69	0 - 20	-1.250
No	8.79	5.06	1 - 18	(p=.212)
Adult Relations				- ,
Yes	9.50	4.77	0 - 20	.636
No	9.96	4.69	2 - 19	(p=.525)

T-tests Between Profile of Mood States-Fatigue^a and Categorical Environmental Demands (n=359)

* Profile of Mood States-Fatigue Instrument Range - 0 - 20

Appendix Q - continued

T-tests Between Profile of Mood States -Fatigue^a and Categorical Environmental Demands (n=359)

External Environmental Demands continued

	<u>Mean</u>	<u>SD</u>	Sample	<u>T-Test</u>
People in Household (in	addition to resp	ondent)		
0-1	9.48	4.6	0 - 20	.401
≥2	9.7	5.0	0 - 20	(p=.689)
Presence of Children <5	years old			
Yes	9.71	4.8	0 - 20	.385
No	9.49	4.7	0 - 20	(p=.701)
Military Occupational Sp	pecialty			
Clerical Jobs	9.45	4.8	0 - 20	.537
Other Jobs	9.73	4.7	1 - 20	(p=.591)
Occupational Fatigue				
0-1	10.46	4.7	0 - 19	-2.479
≥2	9.13	4.7	0 - 20	(p=.014)
Works on Weekends				
Yes	10.08	4.6	1 - 20	2.006
No	9.07	4.8	0 - 20	(p=.046)
Works at Night				
Yes	9.98	4.5	2 - 20	1.297
No	9.30	4.9	0 - 19 Banaa	(p=.195)
Satisfaction with Work S	Situation		<u>Range</u>	
Yes	11.10	4.6	2 - 20	4.423
No	8.80	4.6	0 - 19	(p<.001)
Rank				
Officer	9.26	4.2	2 - 17	.356
Enlisted	9.58	4.8	0 - 20	(p=.722)
Ethnicity				
White	9.53	4.7	0 - 20	175
Non-white	9.62	4.84	0 - 20	(p=.861)

^aProfile of Mood States-Fatigue Instrument Range - 0 - 20

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Pearson Product Moment Correlations Between Visual Analog Scale Energy and Environmental Demands (n=359)

			Interna	d Environment	al Deman	ds	
Depression	Anxiety	Sleep Disturbance	Age Hema 28 W	atocrit Hem eeks 28 W	oglobin 'eeks	Body Mass Index 2 nd Trimester	
31**	151**	39**	.22** .062	082		019	
Caffeine	Moderate Exercise	Strenuous Exercise					
060		111.	Externá	al Environment	al Deman	lds	
Social Support	Partner Support	Friend Support	Number in Household	Work Hours Per Week	Occup: Index	ational Fatigue	Role Demand
.21**	**01.	.10	.056	.068	041		.239**
Night/Duty Hours	Income	Schoo in Years	l Posit Life Change	ive Nega s Life Change:	tive		
022	**61.	.11	.10	35**			
Note: **p<.	01						

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Appendix S

	Internal Env	vironmental De	mands	
	Mean	<u>SD</u>	<u>Sample</u> Range	<u>T-Test</u>
Tobacco Use				
No exposure	192.3	103.0	0 - 500	016
Exposure	192.4	89.0	10 - 390	(p=.987)
Alcohol Use				
No exposure	193.7	98.3	0 - 500	1.284
Exposure	159.6	70.4	50 - 280	(p=.200)
Prenatal Vitamins				
No exposure	208.1	92.9	10 - 440	1.083
Exposure	189.8	96.8	0 - 500	(p=.279)
	External En	vironmental De	emands	
Marital Status				
Married	202.0	92.2	10 - 500	2.366
Not Married	177.2	104.0	0 - 500	(p=.019)
Housing				
Military	182.8	91.0	0 - 500	1.256
Civilian	196.7	100.0	10 - 500	(p =.210)
Role Demands				
Homemaking				
Yes	195.9	97.3	10 - 500	-2.488
No	146.9	89.3	0 - 390	(p=.013)
Student				
Yes	212.9	92.9	20 - 500	-2.408
No	185.0	98.2	0 - 500	(p=.017)
Volunteering				
Yes	223.2	104.5	30 - 480	-2.568
No	186.8	95.3	10 - 500	(p=.011)
Parenting				
Yes	209.6	94.7	0 - 480	-2.076
No	186.4	98 .1	10 - 500	(p=.039)
Leisure Activity				
Yes	194.2	97.1	0 - 500	854
No	181.7	100.2	20 - 460	(p=.393)
Adult Relations*				
Yes	198.8	96.1	10 - 500	-3.013
No	154.5	98.9	0 - 460	(p=.003)

T-tests Between Visual Analog Scale-Energy^a and Categorical Environmental Demands (n=359)

^aVisual Analog Scale-Energy Instrument Range - 0 - 500

Appendix S - continued

T-tests Between Visual Analog Scale-Energy^a and Categorical Environmental Demands (n=359)

External Environmental Demands continued

	<u>Mean</u>	<u>SD</u>	Sample	<u>T-Test</u>
People in Household (in	addition to resp	ondent)		
0-1	187.7	101.0	0 - 500	1.364
≥2	202.9	87.8	40 - 480	(p=.173)
Presence of Children <5	years old			
Yes	209.5	91.0	40 - 480	1.951
No	186.5	98.9	0 - 500	(p=.052)
Military Occupational Sp	ecialty			
Clerical Jobs	197.0	95.0	0 - 500	-1.214
Other Jobs	184.0	102.0	10 - 500	(p=.225)
Occupational Fatigue				
0-1	184.1	96.0	0 - 440	1.075
≥2	196.1	98.0	10 - 500	(p=.283)
Works on Weekends				
Yes	186.7	94.0	0 - 500	-1.035
No	197.4	100.2	10 - 500	(p=.302)
Works at Night				`
Yes	188.9	91.0	0 - 460	502
No	194.3	101.0	10 - 500	(p=.616)
Satisfaction with Work S	ituation			
Yes	179.1	98.0	10 - 460	-1.799
No	198.8	97.0	0 - 500	(p=.073)
Rank				
Officer	217.4	115.0	30 - 440	1.497
Enlisted	190.0	95.0	0 - 500	(p=.135)
Ethnicity				
White	196.9	89.0	10 - 480	1.142
Non-white	184.7	111.0	0 - 500	(p=.254)

^aVisual Analog Scale-Energy Instrument Range - 0 - 500

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Pearson Product Moment Correlations Between Profile of Moods States- Vigor and Environmental Demands (n=359)

			Interna	al Environmer	ital Deman	ds	
Depression 24**	Anxiety 14**	Sleep Disturbance 43**	Age Hem 28 W .076 .10	atocrit Her /eeks 28 . .11	noglobin Weeks	Body Mass Index 2 nd Trimester .030	
Caffeine 016	Moderate Exercise .054	Strenuous Exercise .19**					
			Extern	al Environme	ntal Demar	spi	
Social Support .15*	Partner Support .12	Friend Support .10	Number in Household .032	Work Hour Per Week .071	s Occups Index 092	ational Fatigue	Role Demand 155*
Night/Duty Hours	Income	Schoo in Years	l Posit Life Change	ive Neg s Life Chang	zative jes		
.006	.18*	.047	.082	34**			
Note: *p<.0 **p<.6	1001						

Appendix U

	Internal En	vironmental De	emands	
	<u>Mean</u>	<u>SD</u>	<u>Sample</u> Range	<u>T-Test</u>
Tobacco Use			Tungo	
No exposure	6. 78	3.7	0 - 17	.471
Exposure	6.60	3.6	0 - 16	(p=.638)
Alcohol Use				-
No exposure	6.72	3.67	0 - 17	.291
Exposure	6.43	3.96	2 - 14	(p=.771)
Prenatal Vitamins				-
No exposure	6.56	3.64	1 - 14	252
Exposure	6.72	3.69	0 - 17	(p=.802)
Marital Status				_
Married	7.05	3.7	0 - 17	2.242
Not Married	6.17	3.5	0 - 16	(p=.026)
Housing				
Military	6.44	3.2	0 - 14	.930
Civilian	6.83	3.9	0 - 17	(p =.353)
Role Demands				
Homemaking				
Yes	6.79	3.69	0 - 17	-1.466
No	5.69	3.43	1 - 12	(p=.143)
Student				
Yes	7.32	3.60	0 - 16	-1.883
No	6.49	3.69	0 - 17	(p=.061)
Volunteering				
Yes	7.58	3.60	1 - 15	-1.921
No	6.55	3.67	0 - 17	(p=.056)
Parenting				
Yes	6.83	3.64	0 - 16	309
No	6.70	3.69	0 - 17	(p=.757)
Leisure Activity				
Yes	6.82	3.72	0 - 17	-1.445
No [·]	6.03	3.38	0 - 16	(p=.149)
Adult Relations				
Yes	6.86	3.73	0 - 17	-1.899
No	5.80	3.21	0 - 14	(p=.058)

T-tests Between Profile of Moods States-Vigor^a and Categorical Environmental Demands (n=359)

^aProfile of Moods States - Energy Instrument Range - 0 - 20

Appendix U - continued

T-tests Between Profile of Moods States-Vigor^a and Categorical Environmental Demands (n=359)

E	xternal Environ	mental Demar	nds continued	
	Mean	<u>SD</u>	<u>Sample</u> Range	T <u>-Test</u>
People in Household (in	addition to resp	ondent)	0	
0-1	6.59	3.7	0 - 17	.903
≥2	6.97	3.6	0 - 16	(p=.367)
Presence of Children <5	years old			
Yes	6.79	3.5	0 - 16	.247
No	6.68	3.7	0 - 17	(p=.805)
Military Occupational S	pecialty			
Clerical Jobs	6.82	3.6	0 - 17	731
Other Jobs	6.52	3.7	0 - 16	(p=.465)
Occupational Fatigue				
0-1	6.25	3.6	0 - 15	1.596
≥2	6.92	3.7	0 - 17	(p=.111)
Works on Weekends				
Yes	6.23	3.5	0 - 16	-2.344
No	7.14	3.7	0 - 17	(p=.020)
Works at Night				
Yes	6.43	3.5	0 - 15	-1.100
No	6.87	3.8	0 - 17	(p=.272)
Satisfaction with Work	Situation			
Yes	6.33	3.8	0 - 16	-1.347
No	6.89	3.6	0 - 17	(p=.179)
Rank				
Officer	7.16	4.5	0 - 15	.716
Enlisted	6.67	3.6	0 - 17	(p=.474)
Ethnicity				
White	7.10	3.6	0 - 17	2.627
Non-white	6.06	3.7	0 - 16	(p=.009)

*Profile of Moods States - Energy Instrument Range - 0 - 20

Pearson Product Mon	nent (Correls	ations B	etween ¹	Visual A	nalog Sca	le (VAS)-]	Energy and	l Significa	unt Univ	/ariate Into	ernal and External
	-	7	ß	4		nmental D	emanus (r 7	(*cc=1 8	6	10	11	12
1.VAS-Energy		31*	16**	41**	.22**	11.	.22**	.24**	.21**	.12	36**	.074
2.Depression			.64**	.41**	13*	.002	30**	17*	15*	11	.54**	109
3.Anxiety				.38#	•11	.046	14*	11	077	053	.41**	072
4.Sleep Disturbance					13	-009	22**	15*	14*	14	.41*	093
5.Age						056	010	.332**	.59**	.57**	040	.17*
6.Strenuous Exercise							.066	.012	000	011	020 .	000
7. Social Support								.041	.12	.017	36**	.054
8.Role Demands									.29**	.21*	105	.121
9.Income										.52**	60 [.] -	.196*
10.School											019	.183*
11.Negative Life Event:	70											106*
12.Hemoglobin 28 weel	S											
Note: *p<.01 **p<.0	01											

Appendix V

	Hierarchical Linear Multiple Regression	ı Analy	sis: Dependent	/ariable - Vis	sual Analog S	cale-Energy (n	= 359)
Step	Variable	df	Beta Cum R ²	sr2	R ² Chg	F-Value	p-value
-	Internal Environmental Demands	5	.235		.235	21.720	0000.
	Depression	1	215	.0253		11.7443	.001
	Anxiety	1	.124	.0088		4.1087	.043
	Sleep Disturbance	1	345	.0954		43.9834	000
	Age	1	.163	.0256		11.7923	.001
	Strenuous Exercise	1	.109	.0118		5.4709	.020

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Appendix W

	Hierarchical Linear Multiple Kegressio	n Analy	sis: Dependent Vari	able - Visual Analog S	cale-Energy (n=	(666 =
Step	Variable	df	Beta Cum R ²	sr ² R ² Chg	F-Value	p-value
5	External Environmental Demands	6	.305	.070	10.240	0000
	Social Support	1	.076	.004	2.088	.149
	Role Demands	1	.120	.0110	5.212	.023
	Income	1	.068	.002	1.128	.289
	School	1	077	.003	1.7265	.190
	Negative Life Events	1	192	.023	10.819	.00
	Married	1	055	.002	1.075	.300
	Presence of Children < 5 years old	1	.036	6000.	.4637	.497
	Works of Weekends	1	016	.0002	.1102	.740
	Ethnicity	1	053	.002	1.1620	.282

Appendix W - continued

350) Ľ ۲ Anducia: Denendent Variable • Multiple D Liss I T U:S

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	Hierarchical Linear Multiple Regressi	on Anal	ysis: De _l	pendent Varia	ıble - Vis	ual Analog S	scale-Energy (r	1= 359)
Step	Variable	df	Beta	Cum R ²	sr^2	R ² Chg	F-Value	p-value
_	External Environmental Demands	6		.200		.200	9.208	0000
	Social Support	1	.110		600 [.]		4.028	.046
	Role Demands	1	.163		.0213		8.803	.003
	Income	1	.122		600.		3.556	.060
	School	1	.013		.000		.0502	.823
	Negative Life Events	1	299		.0756		31.382	000 [.]
	Married	П	044		.001		.6336	.427
	Presence of Children <5 years old	1	.050		.002		.8281	.363
	Works of Weekends	l	037		.001		.5670	.452
	Ethnicity .	1	032		6000.		3782	.539

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Appendix X

	Hierarchical Linear Multiple Regressio	n Analy	sis: Depe	ndent Variab	le - Visu	ial Analog Sci	ale-Energy (n=	359)
Step	Variable	df	Beta C	um R ²	sr2	R ² Chg	F-Value	p-value
5	Internal Environmental Demands	2	C !	805		.105	1240	0000
	Depression	1	117		900.		2.9929	.085
	Anxiety	1	.159		.0142		6.7029	.010
	Sleep Disturbance	F	306		.066		31.427	000 [.]
	Age	1	.151		.0121		5.669	.018
	Strenuous Exercise	1	.103		.0104		4.923	.027

Appendix X continued

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Appendix Y

Internal Environmental Demands of Term and Preterm Labor (n=359)

	<u>Term Labor</u>		Preterm La	<u>abor</u>		
Variable (Instrument)	Mean (SD)	Sample Range	Mean (SD)) Sample Range	Instrumer Range	nt T- Test
Depression (Profile of Mood	4.2 (4.1)	0 - 18	3.9 (3.7)	0 - 12	(0 - 20)	433 (p=.67)
Anxiety (Profile of Mood S	5.2 (3.8) states)	0 - 18	4.9 (2.9)	0 - 12	(0 - 20)	1.353 (p=.177)
Sleep Disturbance (Sleep Disturbance	49.8 (15.5 Scale)) 8 - 91	43.7 (16.5)	16 - 80	(-13 -133)	-2.531 (p=.012)
Age	23.8 (4.7)	18 - 40	25.4 (5.3)	19 - 38		.995 (p=.321)
Food Intake (Hemoglobin)	11.6 (1.1)	7.2 - 14.6	11.7 (1.1)	9.3 - 14.3		.297 (p=.767)
Total Weight Gain	37.6 (14.4) -3.2 - 90	31.7 (12.1)) -1 - 58.9		-2.710 (p=.007)
Body Mass Index (End of Pregnancy	29.7 (3.9))	19.4 - 41.8	28.1 (4.2)	21.6 - 39.	1	-2.553 (p=.011)
Total Weight Gain Considering Gesta	.94 (.36) tion	08 - 2.2	.86 (.33)	03 - 1.73		-1.516 (p=.130)

Appendix Y - continued

Variable (Instrument)	<u>Term Labor</u> Number (Percent)	<u>Preterm Labor</u> Number (Percent)	χ²
Food Intake			
(Hemoglobin)			
<10 mg/dl	15(4.9)	4(8.2)	.898 (p=.343)
>13.9 mg/dl	8 (2.6)	2 (4.1)	.337 (p=.562)
Prenatal Vitamins			<i>u</i> ,
Yes	272(85.5)	46 (14.5)	1.020
No	33(91.7)	3(8.3)	(p=.313)
Smoking (Health Habits Questionnaire)	122 (39.5)	22(44.0)	.366 (p=.545)
Alcohol (Health Habits Questionnaire)	13 (4.2)	1(2.0)	.559 (p=.454)
Caffeine Intake	>3/week=137 (44 3)	15(30.0)	3 623
(Health habits	<3/week=172(557)	35(70.0)	(n=057)
Questionnaire)	(3) WOOK 172 (33.7)	33(70.0)	(p .057)
Moderate Exercise			
Level 0 (none)	204 (66.2)	31 (62.0)	2.523
Level 1 (1 - 60 min)	52 (16.9)	10 (20.0)	(p=.641)
Level 2 (61-120 min) 29 (9.4)	6 (12.0)	
Level 3 (121-180 mi	n) 17 (5.5)	1 (2.0)	
Level 4 (>180)	6 (1.9)	2 (4.0)	
Strenuous Exercise			
Level 0 (none)	141 (45.6)	24 (48.0)	1.940
Level 1 (1-60 min)	66 (21.4)	8 (16.0)	(p=.747)
Level 2 (61-120 min) 47 (15.2)	6 (12.0)	
Level 3 (121-180 mi	n) 25 (8.1)	6 (12.0)	
Level 4 (>180 min)	30 (9.7)	6 (12.0)	

Internal Environmental Demands of Term and Preterm Labor (n=359)

Appendix Z

(Social Sup	port a	nd Role	Variables)			
Variable (Instrument)	<u>1 err</u> Mea	<u>n Labo</u> in (SD)	<u>r</u> Sample Range	Preterm Labor Mean (SD) Sample Range	Instrument Range	T- Test
Social Support (Social Behavior In or SBI)	104.1 dex	(20.1)	43-132	104.3 (18.7) 56 - 132	(12 - 132)	.090 (p=.929)
Social Support Partner (SBI)	52.0	(15.3)	11 - 66	50.2 (16.1) 11 - 66	(6 - 66)	783 (p=.434)
Social Support Friend/Rela (SBI)	52.0 tive	(11.7)	11 - 66	54.1 (15.3) 25 - 66	(6 - 66)	1.213 (p=.226)
Role Demar	nds 3.45	(1.13) 0-6	3.35 (.90) 0-6	(0 - 6)	508 (p=.612)

Appendix Z - continued

(Housing Variable	es)		
Variable	<u>Term Labor</u> Number (Percent)	<u>Preterm Labor</u> Number (Percent)	χ²
Housing (Demographics)	Military= 98 (31.7) Civilian= 211(68.3)	15 (30.0) 35 (70.0)	.059 (p=.809)
Role Demand	Homemaking=285(92.2)	48(96.0)	.909
1005	Student=84(27.2)	11(22.0)	(p=.340) .594 (p=.441)
	Volunteering=45(14.6)	10(20.0)	.981 (p=.322)
	Parenting=94(30.7)	15(31.3)	.005 (p=.941)
	Leisure=264(85.4)	43(86.0)	.011 (p=.916)
	Adult Rel=263(86.0)	44(88.0)	.194 (p=.659)
Total Number	0 - 1= 213 (68.9)	36 (72.0)	.191
of People in Household (Demographics)	>1 = 96 (31.1)	14 (28.0)	(p=.662)
Presence of Children < 5 y/o	77 (24.9)	14 (28.0)	.216 (p=.642)
Presence of Children ≤3 y/o	62 (20.1)	9(18.0)	.116 (p=.734)

External Environmental Demands of Term and Preterm Labor (n=359)

Appendix Z - continued

External Environmental Demands of Term and Preterm Labor (n=359)

(Occupational Co	onditions Varia Term Labor	ables)	Preterm La	bor		
Variable (Instrument)	Mean (SD)	Sample Range	Mean (SD)	Sample Range	Instrumer Range	nt T- Test
Occupational Fatigue Index (OFI)	1.2 (.94)	0 - 5	1.3 (1.0)	0 - 4	0 - 5	.907 (p=.365)
Hours Work Per Week (Demographics)	42.7 (7.1)	13 - 66	42.7 (5.4)	23 - 56		.049 (p=.961)

ARA BRARY Solution

Appendix Z - continued

External Environmental Demands of Term and Preterm (n=359)

(Occupational Conditions Variables)

Variable	<u>Term Labor</u> Number (Percent)	<u>Preterm Labor</u> Number (Percent)	χ²
Satisfaction With Work (Demographics)	103 (33.3)	14 (28.0)	.557 (p=.455)
Works on Weekends	145 (46.9)	25 (50.0)	.163 (p=.686)
Works at night (Demographics)	109 (35.3)	22(44.0)	1.414 (p=.234)
Occupational Fatigue Dicho- tomized (OFI)	≥2 = 216 (69.9) <2 = 93 (30.1)	31 (62.0) 19 (38.0)	1.252 (p=.263)
Posture (eg. long standing)	90 (29.1)	0 (40.0)	2.394 (p=.122)
Physical Exertion (eg. heavy lifting)	23 (7.4)	5 (10.0)	.391 (p=.532)
Industrial Machine Work (eg. welding)	3(1.0)	1 (2.0)	.414 (p=.520)
Mental Stress (eg routine tasks)	173(56.0)	26 (52.0)	.277 (p=.599)
Environmental Stress (eg. cold, heat, humidity)	66 (21.4)	12 (24.0)	.176 (P=.674)

Appendix Z - continued

External Environmental Demands of Term and Preterm Labor (n=359)

(Stressors/ Socio-	-Econo	<u>mic Va</u>	riables)					
	<u>Term</u>	Labor		<u>Preter</u>	<u>m Lab</u>	or		
Variable	Mea	n (SD)	Sample	Mean	(SD)	Sample	Instrume	nt T-
(Instrument)			Range]	Range	Range	Test
Positive Life Event Change (Life Events Questionnaire-LH	14.5 EQ)	(10.6)	0 - 68	12.9	(8.2)	2 - 41	(0 - 246+)	-1.062 (p=.289)
Negative Life Events Change (LEQ)	10.2	(9.5)	0 - 53	12.2	(10.6)	0 - 36	(0 - 246+)	1.324 (p=.186)
Education (Demographics)	12.0	(1.5)	11 - 20	13.2	(2.1)	12 - 20) (0 - 20+)	1.329 (p=.185)
Income (Demographics) (14 levels)	7.4	(2.9)	1 - 14	7.6	(3.7)	1 - 14	4 (1 - 14)	.595 (p=.553)
Years in Service (Demographics)	4.1	(3.2)	.7 - 15	4.1	(3.6)	.3 - 18	3	.028 (p=.977)
Variable	T N	<u>erm La</u> lumber	<u>bor</u> (Percent)		<u>Preter</u> Numb	m Labor er (Perce	ent)	χ²
Marital (Demographic)	M N	farried lot Mar	= 185 (59.9 ried = 124 (') (40.1)	34(68 16(32	8.0) .0)		1.196 (p=.274)
Rank (Demographic)	C E	Officer	= 22 (7.1) = 287(92.)	9)	9(18 41(82	8.0) 2.0)		6.458 (p=.011)
Ethnicity (Demographic)	V N	Vhite = lot Whi	194 (63.0) te = 114) (37.0)	28(56 22(44	5.0) .0)		.891 (p=.345)

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Appendix AA

	<u>Term Birth</u>	Preter	<u>m Birth</u>			
Variable (Instrument)	Mean (SD)	Sample Range	Mean (SD)	Sample Range	Instrument Range	t T- Test
Depression (Profile of Mood States)	4.14 (3.98)	0 - 18	4.44 (4.63)	0 -18	(0 - 20)	41 (p=.68)
Anxiety (Profile of Mood States)	5.13 (3.69)	0 - 18	5.05 (3.46)	0 - 13	(0 - 20)	.12 (p=.90)
Sleep Disturbance (Sleep Disturbance Scale)	49.5 (15.5) e	8 - 91	43.8 (17.8)	16 - 8	(-13 -133)	-2.011 (p=.045)
Age	23.8 (4.7)	18 - 40	25.4 (5.3)	20 - 38		1.818 (p=.07)
Food Intake (Hemoglobin)	11.6 (1.1)	7.2-14.6	11.9 (1.1)	9.8-14.3		(p=.13)
Total Weight Gain	37.3 (14.2)	-3.2 - 90	31.4 (13.8)	-1 - 58.9		-2.299 (p=.02)
Body Mass Index (End of Pregnancy	29.6 (4.0))	19.4 - 41.8	28.2 (4.0)	21.7 - 36	5.2	-1.868 (p=.063)
Total Weight Gain Considering Gesta	.94 (.35) tion)08 - 2.2	.89 (.39)	03 - 1.′	79	68 (p=.497)

Internal Environmental Demands of Term and Preterm Birth (n=359)

Appendix AA - continued

Variable (Instrument	<u>Term Birth</u>) Number (Percent)	<u>Preterm Birth</u> Number (Percent)	χ²
Food Intake			
(Hemoglobin)			
<10 mg/dl	17 (5.3)	2 (5.9)	.022 (p=.882)
>13.9 mg/dl	9 (2.8)	1 (2.9)	.002 (p=.961)
Prenatal Vitamins			u
Yes	287(89)	34 (94.4)	.673
No	31 (9.7)	2 (5.7)	p=.412
Smoking (Health Habits Questionnaire)	132 (40.6)	12 (35)	.363 (p=.547)
Alcohol (Health Habits Questionnaire)	12 (3.7)	2(5.9)	.394 (p=.530)
Caffeine Intake	≥3/week=139 (42.8)	13(38.2)	.259
(Health habits Questionnaire)	<3/week=186 (57.2)	21(61.8)	(p=.611)
Moderate Exercise			
Level 0 (none)	215 (66.4)	20 (58.8)	5.381
Level 1 (1 - 60 min) 54 (16.7)	8 (23.5)	(p=.25)
Level 2 (61-120 mi	n) 31 (9.6)	4 (11.8)	`
Level 3 (121-180 m	un) 18 (5.6)	0	
Level 4 (>180)	6 (1.9)	2 (5.9)	
Strenuous Exercise			
Level 0 (none)	146 (44.9)	19 (55.7)	3.451
Level 1 (1-60 min)	71 (21.8)	3 (8.8)	(p=.485)
Level 2 (61-120 mi	n) 48 (14.8)	5 (14.7)	
Level 3 (121-180 m	in) 28 (8.6)	3 (8.8)	
Level 4 (>180 min)	32 (9.8)	4 (11.8)	

Internal Environmental Demands of Term and Preterm Birth (n=359)

Appendix BB

External Environmental Demands of Term and Preterm Birth (n=359)

Variable (Instrument)	<u>Term Birth</u> Mean (SD) Sample Range	<u>Preterm Birth</u> Mean (SD) Sampl Range	e Instrument. Range	T- Test
Social Support (Social Behavior Inc or SBI)	104.0 (19.8) 43 - 132 lex	105.1 (20.9) 56 - 13	2 (12 - 132)	.318 (p=.751)
Social Support Partner (SBI)	51.7 (15.3) 11 - 66	52.3 (19.8) 11 - 66	(6 - 66)	.193 (p=.847)
Social Support Friend/Relat (SBI)	52.3 (11.5) 11 - 66 ive	52.8 (10.6) 22-66	(6 - 66)	.293 (p=.769)
Role Deman	ds 3.35 (1.11) 0 - 6	3.50 (.98) 0 - 6	(0 - 6)	743 (p=.458)

(Social Support and Role Variables)

Appendix BB - continued

(Housing Variables)					
	<u>Term Birth</u>	Preterm Birth			
Variable	Number (Percent)	Number (Percent)	χ^2		
Housing	Military= 104 (32.0)	9 (26.5)	.436		
(Demographics)	Civilian= 221 (68.0)	25 (73.5)	(p=.436)		
Role Demand Jo	bs				
	Homemaking=300(92.3)	33(97.1)	1.034 (p=.309)		
	Student-85(26.2)	10(29.4)	.168 (p=.682)		
	Volunteering=47(14.5)	8(23.5)	1.951 (p=.162)		
	Parenting=102(31.7)	7(21.9)	1.312 (p=.252)		
	Leisure=279(85.8)	28(82.4)	.303 (p=.582)		
	Adult Relations=275(85.1) 32(94.1)	2.059 (p=.151)		
Total Number	0 - 1= 222 (68.3)	27 (79.4)	1.786		
of People in Household (Demographics)	>1 = 103 (31.7)	7 (20.6)	(p=.181)		
Presence of Children < 5 y/o	84 (25.8)	7 (20.6)	.450 (p=.502)		
Presence of Children ≤3 y/o	67 (20.6)	4 (11.8)	1.520 (p=.218)		

External Environmental Demands of Term and Preterm Birth (n=359)

Appendix BB - continued External Environmental Demands of Term and Preterm Birth (n=359)

(Occupational Conditions Variables)

	<u>Term Birth</u>		Preterm Bir	Preterm Birth		
Variable (Instrument)	Mean (SD)	Sample Range	Mean (SD)	Sample Range	Instrument. Range	T- Test
Occupational Fatigue Index (OFI)	1.12 (.98)	0 - 5	1.17 (.95)	0 - 3	(0 - 5)	319 (p=.750)
Hours Work Per Week (Demo- graphics)	42.6 (6.9)	0 - 24	42.9 (6.8)	0 - 16		.201 (p=.841)

Appendix BB - continued

External Environmental Demands of Term and Preterm Birth (n=359)

(Occupational Conditions Variables)

Variable	<u>Term Birth</u> Number (Percent)	<u>Preterm Birth</u> Number (Percent)	χ²
Satisfaction With Work (Demographics)	105 (32.3)	12 (35.3)	.125 (p=.724)
Works on Weekends (Demographics)	153 (47.1)	17 (50.0)	.105 (p=.885)
Works at night (Demographics)	117 (36.0)	14 (41.2)	.356 (p=.551)
Occupational Fatigue Dicho- tomized (OFI)	$\geq 2 = 223 (68.8)$ <2 = 102 (31.4)	24 (70.6) 10 (29.4)	.056 (p=.813)
Posture (eg. long standing)	100 (30.8)	10 (29.4)	.027 (p=.870)
Physical Exertion (eg. heavy lifting)	26 (8.0)	2 (5.9)	.192) (p=.813)
Industrial Machine Work (eg.welding)	3 (0.9)	1 (2.9)	1.138 (p=.286)
Mental Stress (eg routine tasks)	180 (55.4)	19 (55.9)	.003 (p=.956)
Environmental Stress (eg. cold, heat, humidity)	72 (22.2)	6 (17.6)	.368 (p=.544)

Appendix BB - continued

External Environmental Demands of Term and Preterm Birth (n=359)

(Stressors/ Soc	io-Economi	c Variables)				
	Term Birth		Preterm Bir	<u>th</u>		
Variable	Mean (SD)	Sample	Mean (SD)	Sample	Instrument.	T-
(Instrument)		Range		Range	Range	Test
Positive Life Event Change (Life Events	14.5 (10.5)	0 - 68	12.2 (7.14)	2 -31	(0 - 246+)	1.981 (p=.221)
Questionnaire-	LEQ)					
Negative Life Events Change (LEQ)	10.7 (9.5)	0 - 53	11.8 (10.6)	0 - 35	(0 - 246+)	.629 (p=.53)
Education (Demographic	12.9 (1.5) s)	11 - 20	13.4 (2.3)	12 - 20	(0 - 20+)	1.981 (p=.048)
Income (Demographics (14 levels)	7.3 (2.9) s)	1 - 14	8.4 (3.5)	1 - 14	(1 - 14)	1.255 (p=.21)
Years in Service (Demographics	4.1 (3.6) 0 s)	.3 - 18	4.6 (3.6)	0.8 - 15		.795 (p=.427)
(Demographic	s)					

Variable	<u>Term Birth</u> Number (Percent)	<u>Preterm Birth</u> Number (Percent)	χ²
Marital	Married = 194 (59.7)	25 (73.5)	2.477
(Demographic)	Not Married = $131 (40.3)$	9 (26.5)	(p=.116)
Rank	Officer = $23(7.1)$	8 (23.5)	10.56
(Demographic)	Enlisted = $302(92.1)$	26(76.5)	(p=.001)
Ethnicity	White = $199(61.4)$	23(67.9)	.507
(Demographic)	Not White = $125(38.6)$	11(32.4)	(p=.477)

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