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PRINCIPAL INVESTIGATOR: Maureen C. Hatch, Ph.D.

CONTRACTING ORGANIZATION: Mount Sinai School of Medicine New York, New York 10029

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Maureen Hatch 10/199 PI - Signature Date

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#### **DOD ANNUAL REPORT**

# (5) INTRODUCTION:

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Preterm birth is a major cause of perinatal morbidity and mortality. Nationally about 8% of all deliveries are preterm but the rates in subgroups of the population range from 4% -- which is the rate in many other developed countries -- to as high as 15%. Established risk factors, such as black race and low socioeconomic status, explain less than a third of spontaneous preterm births, so there is considerable interest in identifying significant new determinants of premature delivery. Currently, the potential roles of psychosocial stress and physical strain have attracted attention. These factors may be especially relevant for women who have a marked hemodynamic response to stress.

The overall goal of this study is to examine the effects of physical and psychosocial stress as risk factors for preterm birth among an ethnically diverse population of 1,000 active duty military women recruited from the prenatal clinic at Wilford Hall Medical Center during their first trimester and followed to delivery. A secondary goal is to evaluate the role of the maternal circulatory response to stress in raising the risk for preterm delivery.

# (6) **BODY**:

Tasks 1-7 in the Statement of Work have already been completed. Tasks 8-11, which were scheduled to be pursued during the previous 12-month period, are listed and discussed below.

# Tasks 8 - Enroll subjects and administer protocol.

A total of 641 subjects have been enrolled to date. This puts us only slightly behind our

anticipated enrollment rate. While refusals have been extremely rare, there have been more ineligibles than anticipated. Ineligibility is due largely to women who are either leaving Lackland Air Force Base for another military station or leaving the military altogether prior to the time of delivery. The total number of new active duty OB patients over the past year was 439, close to the number we projected (400-500). However, almost 30% of these end up transferring to another base or separating from the service before they deliver. While others transfer into the system, they are usually too late in gestation to be enrolled.

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From 15 October 98 to 31 August 99, a total of 345 potentially eligible women were contacted and asked to participate in the study. Of these, 9 (3%) refused to participate, 67 (19%) were excluded due to their inability to remain in the San Antonio area through the pregnancy, 10 (3%) presented for prenatal care after the first trimester, and 15 (4%) were excluded due to multiple gestation. These figures are very close to those of last year. A total of 244 pregnant active duty women were enrolled in the study during the above time. This represents 71% of all those approached and 88% of those who were eligible. An additional 15 (6%) were subsequently excluded due to spontaneous pregnancy termination and 6 (2%) due to diagnosed multiple gestation.

Among those who enroll, the protocol has been well accepted. However 5 subjects withdrew prior to the initial questionnaire, stating they were too busy. For the same reason, participation in the cardiovascular testing is averaging only 70% at best. Efforts to accommodate the subjects' time constraints through flexible scheduling have had minimal success.

One modification has been made to the protocol since our initial application. We had planned to use a portable accelerometer to monitor subjects' physical activity over a three day period. However, after further consideration of costs and likely compliance, we decided to eliminate portable activity monitors and to rely on the information from fitness assessments and job-related service codes.

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#### Task 9 - Review, edit and code questionnaires. Enter into data base.

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During the 11 month period from October 15, 1998 to August 31, 1999, 187 women (81%) completed the baseline questionnaire, and 181 (79%) completed the follow-up questionnaire. Thus far questionnaire data have been entered for 511 of the 641 participants currently enrolled. After review of each questionnaire by the Nurse Coordinator, the data are entered into the computer by our research assistant. This is accomplished using a data entry program in Microsoft Access that includes range and internal consistency checks. In addition to the computerized checks, manual reviews are conducted based on samples drawn randomly from batches of questionnaires. One of the Co-PIs then compares the entered data to the actual hard copy. Very few errors have been identified through these random checks and they are quickly corrected.

# Task 10 - Integrate psychophysiological data into main data base.

We have been integrating the psychophysiologic data into the main dataset in batches. The mechanism for doing this has proven to work well.

# Task 11 - Abstract medical records for subjects who deliver.

Of the 244 subjects enrolled during the past year, 215 have had their delivery records abstracted. A total of 18 (8%) delivered preterm, 11 (5%) at less than 35 weeks of gestation.

Based on the cumulative delivery records reviewed to date, the interim preterm delivery rate in our study population as a whole is 8.6% (29/338). The overall rate for the clinic from which we are recruiting, which also includes military spouses and inactive duty military women, is 7%. These estimated rates do not distinguish stressed women from those who are not stressed.

Thus far analysis of the data to address the study's specific aims has not taken place. However

we plan to begin data analysis shortly. In the interim we provide a descriptive profile of the 511 subjects on whom data have been entered.

Race/Ethnicity:	% white	59.5
	black	21.5
	Hispanic	11.9
	Other	7.1
Marital Status:	% married	79.0
	Single	15.5
	Sep/div	5.5
Military Branch:	% Air Force	74.9
	Army	22.7
	Navy	2.4
Age:	% 30+	22.1

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The participants are relatively young, with less than a quarter being age 30 or above. Over three quarters (79%) are currently married or living with a common law partner. However, 21% of subjects are either single (15.5%) or separated/divorced (5.5%). The population is drawn largely from the Air Force but also includes women from the Army (22.7%) and form the Navy (2.4%). The group is ethnically diverse: 59.% white, 21.5% black, 11.9% Hispanic and 7.1% other.

#### (7) KEY RESEARCH ACCOMPLISHMENTS:

• Have achieved an excellent participation rate of 97%, which will contribute importantly to the validity of the study's findings.

- Data have been entered on 511 (80%) of the 641 participants, allowing us to begin data analysis shortly.
- Periodic review of data by the Co-PIs has insured that data quality is high.

# (8) REPORTABLE OUTCOMES:

None as yet.

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# (9) CONCLUSIONS:

The June 1998 issue of Military Medicine included a review of the literature on pregnancy in the military (Tam 1998). The author identified particular stressors in the psychosocial milieu in which active duty pregnancies occur. The data collected in our questionnaire will allow us to examine the impact of these and other stressors on pregnancy outcome in this population.

# (10) REFERENCES:

Tam LW. Psychological aspects of pregnancy in the military: a review. Mil Med 1998;163:408-412.