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Exploring the Stress Response in New Army Nurses

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EXPLORING THE STRESS RESPONSE IN NEW ARMY NURSES

A dissertation submitted in partial fulfillment of the requirements for the degree of
Doctor of Philosophy at Virginia Commonwealth University

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Abstract

EXPLORING THE STRESS RESPONSE IN NEW ARMY NURSES

By Laureen Annette Otto, PhD RN

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy at Virginia Commonwealth University.

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The study of stress is limited in professional nursing, but it is nearly non-existent in professional military nursing. The purpose of this study was to explore the relationships among psychological, environmental, biological and demographic factors of stress in new Army nurses during the Army Medical Department's 8-week Officer Basic Leadership Course (OBLC). Using a descriptive prospective, correlational repeated measures design, 33 study participants completed two psychological stress measures (Perceived Stress Scale [PSS] and the Impact of Event Scale – Revised[IES-R]), an environmental measure (Life Experiences Survey [LES]), a biologic measure (salivary cortisol) and a demographic

questionnaire at three different time points during OBLC: at the beginning of OBLC, during the field training exercise and at the end of OBLC.

The majority of participants were single, Caucasian females under 30 years of age with no RN experience and no deployment experience. No significant gender differences were detected among study variables. A simple (single-group) repeated measures analysis of the PSS scores, IES-R scores, and salivary cortisol was conducted using the LES score as a covariate. While the PSS scores and salivary cortisol levels did not change significantly over time, the IES-R score did change significantly over time ($p = 0.001$). The environmental factor (LES score) was not significant as a covariate in any of the three models.

The unique baseline findings in this study may provide a springboard for further studies in stress particularly with military nurses who will eventually be deployed and experience a variety of stressful events. Longitudinal research could yield important predictive information related to how the stress response evolves over the course of one's military career which may include frequent deployments to the combat zone.

CHAPTER 1 Introduction

Effects of exposure to combat have been shown to have psychological consequences for military personnel, including PTSD, depression, and anxiety (Kaylor, King, & King, 1987; Kulka et al., 1990; Erickson et al., 2001; Wolfe, Schnurr, & Brown, 1994.) While overall stress in military personnel has been studied, stress related to military nursing in the combat zone has been limited to retrospective studies of military nurses who served in Vietnam (Baker, Menard, & Johns, 1989; Norman, 1988; Scannell-Desch, 2000.) There are no data that identify early baseline patterns of the stress response, which may relate to the later development of post traumatic stress symptoms, depression or anxiety in military nurses. Further, there is no known research on the relationships among perceived stress, life experiences and biological stress responses in military nurses. Cohen, Kessler, and Gordon (1997) view the stress response as "a process in which environmental demands tax or exceed the adaptive capacity of an organism, resulting in psychological and biological changes that may place persons at risk for disease" (p. 3). This comprehensive approach to understanding the stress response provides a solid framework for understanding the stress response. Therefore, a state-of-the-science literature review with regard to the stress response in the military and nursing is presented (Chapter 2).

Because there are no research studies that describe the relationships among psychological, demographic, environmental and biological factors of stress in military nurses, the purpose of this doctoral research study was to explore the relationships among these factors of stress in new Army nurses. An adaptation of the Cohen stress framework guided this study in understanding the stress response in a sample of new Army nurses attending the 8-week Officer Basic Leadership Course (OBLC). The study design, methods, results and discussion are presented in Chapter 3.

Using a descriptive prospective, correlational repeated measures design to explore these relationships, this study specifically examined, within a sample of new Army nurses, the relationships among selected psychological, environmental, biological and demographic factors related to stress during attendance at the OBLC at Fort Sam Houston in San Antonio, Texas. The OBLC included didactic and clinical skills training in the classroom as well as a potentially stressful 3-week field training exercise (FTX) at Camp Bullis that focused on individual, collective team, and medical training and included convoy training and combat medical field training activities.

A convenience sample of 33 participants, at three specified time points during OBLC, completed two psychological measures, the Perceived Stress Scale (PSS) (Cohen, Kamarck, & Mermelstein, 1983) and the Impact of Event Scale – Revised (IES-R) (Weiss & Marmar, 1997), an environmental measure, the Life Experiences Survey (LES) (Sarason, Johnson & Siegel, 1978), a biological measure (salivary cortisol samples), and a demographic questionnaire. The three time points during OBLC were the beginning of OBLC, during a field training exercise, and at the end of OBLC.

The majority of participants were single, Caucasian females under 30 years of age with no RN experience and no deployment experience. No significant gender differences were detected among study variables. A simple repeated measures analysis of the PSS scores, IES-R scores, and salivary cortisol was conducted using the LES score as a covariate. While the PSS scores and salivary cortisol levels did not change significantly over time, the IES-R score did change significantly over time ($p = 0.001$). The environmental factor (LES score) was not significant as a covariate in any of the three analytic models.

The unique baseline findings in this study may provide a springboard for further studies in stress particularly with military nurses who will eventually be deployed and experience a variety of stressful events. Longitudinal research could yield important predictive information related to how the stress response evolves over the course of one's military career which may include frequent deployments to the combat zone.

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CHAPTER 2 Describing the Stress Response

in the Military and Nursing

Describing the Stress Response in the Military and Nursing:

A Literature Review

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The views expressed in this paper are those of the author and do not necessarily represent the official policy or position of the Department of Defense (paragraph 4-3, AR 360-5) or the U.S. Army Medical Command.

Abstract

The study of stress is limited in professional nursing, but it is nearly non-existent in professional *military* nursing. The purpose of this literature review is to present a review of the stress response in the military and nursing. Understanding the stress response provides military leadership with science-based evidence and directions in how best to care for and retain the nation's military and nursing workforce. Future research should address optimal coping strategies and other stress-reduction interventions for military service members at different critical stress time points throughout their military careers.

Background

Understanding stress in active duty military and veteran populations has become a national concern. In April, 2008, five years after the start of the war in Iraq, RAND Corporation (Territanielian & Jaycox, 2008), a nonprofit research organization, reported that nearly 20 % (approximately 300,000) of military service members who have returned from Iraq and Afghanistan report symptoms of post traumatic stress disorder (PTSD) or major depression costing the nation as much as $6.2 billion (direct medical care and costs for lost productivity and suicide) in the two years following deployment.

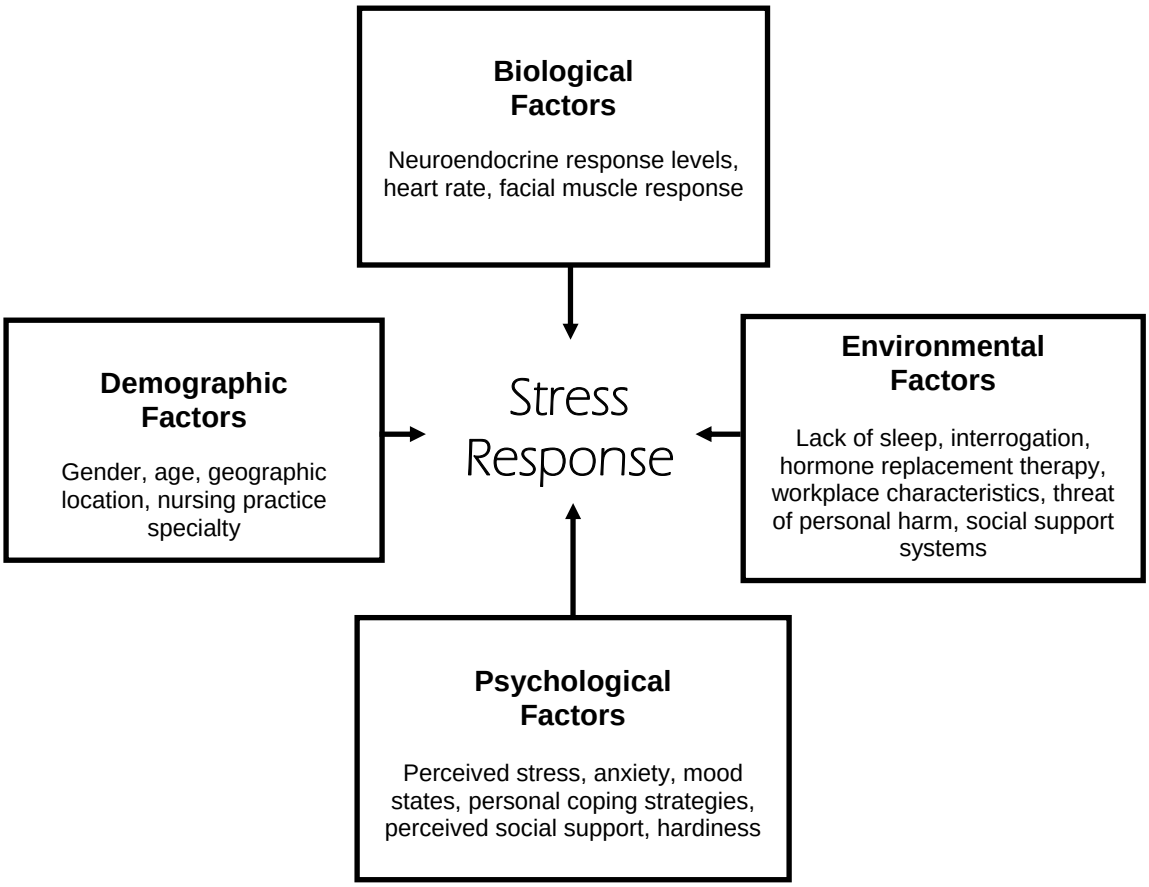
The effects of exposure to combat have been shown to have physical and psychological consequences including PTSD, depression, and anxiety, as well as other health outcomes, both acute and chronic (Kaylor, King, & King, 1987; Kulka et al., 1990; Erickson et al., 2001; and Wolfe, Schnurr, & Brown, 1994.) While overall stress in the military has been studied, studies of stress in military nursing in the combat zone, for the most part, have been limited to retrospective studies of military nurses who served in

Vietnam (Baker, Menard, & Johns, 1989; Norman, 1988; Scannell-Desch, 2000). These studies revealed difficulty in coping with stressful situations, the experience of PTSD, and the development of personal strategies in dealing with the hardships experienced in combat nursing. Recently, stress has been studied in nurses in civilian, non-combat settings (Ben-Ezra, Palgi, & Essar, 2007) where a difference in stress symptoms was noted between nurses and physicians in a civilian hospital in Israel that came under hostile fire. Nurses were five times more likely than physicians to experience clinically significant symptoms of posttraumatic stress. In another study (Battles, 2007), initial pilot study findings revealed that 20% of nurses in a New Orleans metropolitan area emergency department had PTSD symptoms during and immediately after Hurricane Katrina.

The military invests heavily in their nursing workforce by educating nurses in specialty areas such as critical care nursing and nurse anesthesia. While military nurses typically incur a service obligation after receiving this specialty education, many nurses leave the military soon after this obligation is complete – at a time when they are most valuable to the military healthcare system. Understanding stress as it is experienced by the military nurse is important because of the significant detrimental health-related outcomes that can result in the military nursing workforce, the potential attrition of highly trained nurses in a profession that is only expected to experience greater shortages, and the potential impact on nurses' performance in the combat zone. Understanding the stress response will provide military nursing leaders with direction in how to optimize military nurses' health outcomes and retain the nation's military nurses.

Research exploring the stress process, particularly from environmental, psychological, and biological approaches, is lacking in the profession of nursing, but is nearly non-existent in military nursing. Moreover, general research that documents biological function, onset, and course of disease as a result of stress in the same individuals is sorely lacking (Daruna, 2004.) Focusing on health outcomes related to stress, Cohen, Kessler, and Gordon (1997) define stress as "the general process through which environmental demands result in outcomes deleterious to health" (p. 4). Expanding on the Lazurus and Folkman (1984) stress model; Cohen et al. recognize three central components in the stress process that include environmental stressors or events, the psychological factors of stress including the subjective appraisal or perception of stress, and the biological responses to stress such as the hormonal response. Research exploring the stress process that includes environmental, psychological and biological components allows for multiple avenues of approach to measuring, assessing, and intervening in order to enhance coping, with the ultimate goal of positively impacting health outcomes. Figure 1 is a proposed model of factors related to the stress response in military nurses. These factors are examined in this review of the literature.

Figure 1. Proposed model of factors related to the stress response in military nurses.



The purpose of this literature review is to present a review of the stress response in the military and nursing. This review will summarize the current understanding of stress in the military and nursing in general and military nursing specifically. Exploring stress in military nurses will provide useful baseline descriptive information that will be critical in examining longitudinally the stress process and health outcomes as they are uniquely experienced by military nurses throughout their military careers. Moreover, this information could dramatically impact military nursing retention efforts as military leadership considers this information in tailoring effective coping and treatment strategies at different critical stress points in a military nurse's career.

The Stress Response during and after Military Actions

The psychological stress of war and its unique combat-related stressors have been studied throughout American history. Terminology used to describe stress in the combat zone has evolved over time. *Shell shock, battle fatigue, combat stress* have each described the psychological symptoms experienced by military members who saw combat action from World War I through Vietnam. In 1980, however, well after the Vietnam War had ended, the diagnosis of *post traumatic stress disorder,* or PTSD, became widely recognized as the syndrome of symptoms that Vietnam veterans were experiencing related to their military service in Vietnam. The diagnosis of PTSD today, however, can reflect the symptoms experienced by anyone who may have been exposed to a variety of traumatic events, including the experience of the combat zone, as well as those related to natural disasters, childhood abuse, or terrorist events.

The Stress Response and the Military Veteran

Research in the 1980s and 1990s related to PTSD explored not only the prevalence of PTSD but also the physical and psychosocial health, and personal characteristics such as hardiness and resilience and their relationships to the stress response. In 1990, the Veterans Administration sponsored a 4-year, $9 million assessment of the extent and implications of PTSD in military service in Vietnam (Kulka et al.). Named the National Vietnam Veterans Readjustment Study, this research concluded that a significant number of Vietnam veterans were suffering from psychological problems as well as experiencing life-adjustment problems including work-related and marital problems. Of veterans who served in Vietnam, approximately 15.2% of males and 8.5% of females met the criteria for current PTSD, while those with high levels of combat exposure had significantly higher rates of PTSD, with 35.8% of men and 17.5% of women meeting the criteria for current PTSD. Depression, anxiety, and alcohol problems were also prevalent at greater rates among PTSD sufferers than among their civilian counterparts. Also in the 1980s, Kaylor, King, and King (1987) conducted a meta-analysis of 67 studies that examined the psychological status of Vietnam veterans and similarly showed that (in-country) Vietnam veterans manifested poorer socio-psychological health than did (non in-country) Vietnam era veterans and non-veterans.

The relationships among psychosocial factors, PTSD and health outcomes are complex. War zone stressor dimensions, resilience-recovery factors, social resources, other life events and PTSD symptoms were examined using a national sample of Vietnam veterans (n = 1,632) (King et al., 1998). The researchers found evidence of the mediation

effects of hardiness, postwar structural and functional social support, and negative life events after the war. However, moderator effects or buffering between war zone stressor levels and resilience-recovery factors was minimal. Some Gulf War-era military stress studies (Blood & Gaucher, 1993; Perconte et al., 1993) point to direct links between exposure to the stressors of deployment and experiences in the combat zone and higher disease rates among Marines. More recently, researchers (Erickson, Wolfe, & King, 2001) examined links between PTSD and depression over time in a large sample of Gulf War veterans (n = 2,949) upon their return from military service in the Gulf region. They found a reciprocal relationship between PTSD and depression symptomology (re-experiencing and avoidance-numbing symptoms) that was present in followup examinations.

Because the majority of military nurses are women, Bond (2004) points to gender differences in health responses to wartime service whereby women are not only more vulnerable to PTSD but they also are at higher risk for certain cancers and other poor health outcomes. Wolfe, Schnurr and Brown (1994) studied the associations of war-zone exposure and PTSD with perceived physical health outcomes in non-treatment seeking female veterans and found that increases in PTSD after war-zone exposure partially mediates the influence of war-zone traumatic exposure on perceived health, thereby supporting the findings of other studies linking the effects of stress to health outcomes. In a study of Gulf War veterans (Vogt et al., 2005), women's experiences of interpersonal stressors had a greater effect on their mental health than did men's experiences. Understanding these differences and how they are related to PTSD and its co-morbidities

can impact health may lead to more effective strategies in coping with stress and thus to improved health outcomes in military nurses.

In addition to the plethora of PTSD research in the veteran population, military stress research over the last 20-plus years has focused on physical and emotional effects of stress related to military service while still serving in the military. Such studies have included primarily training situations while some have explored stress in combat situations. These studies too have shown that the effects of exposure to combat include PTSD, depression, and anxiety. More recent stress studies in the military explore the stress students experience in training situations, for example, military student pilots' stress levels during high-performance military aircraft flight (Leino et al., 1995). Stress responses in pilots that could potentially result in unsuccessful flight missions could mean not only the loss of a highly-trained pilot but also in loss of life on the ground. Understanding pilots' stress responses during flight operations may enhance understanding of the stress response in other occupations typically associated with high stress levels, such as military nursing.

The Stress Response and Military Training Settings

Stress is known to activate the hypothalamic-pituitary-adrenocortical (HPA) and sympathetic-adrenomedullary (SAM) systems contributing to the dysregulation of these systems and the development of disease processes such as depression and chronic migraines (Banki et al., 1992; Nemeroff et al, 1984; Patacchioli et al., 2006.) Biological factors in the stress response have been studied for decades. Researchers have long known that salivary cortisol is a marker for stress based on the HPA response (Gozansky et al., 2005).

Military flight training. In one study, Tarui and Nakamura (1991) explored F-4EJ fighter pilots' hormonal responses (salivary cortisol, 17-OHCS; unbound cortisol; urinary catecholamines and urinary electrolytes) to increased stress during seven repetitive training flight missions. They found that levels of salivary and urinary corticosteroids and urinary catecholamines were each slightly increased during the missions, suggesting moderate flight stress for the pilots flying during repetitive missions. Other researchers (Leino et al., 1995), however, found that basic military flying (versus advanced jet military flying) had no effect on stress hormones, including cortisol, when they evaluated plasma levels of several neuroendocrine hormones in five undergraduate and five senior military pilots of the Finnish Air Force (FAF) performing short-term basic flight missions via a flight simulator and a jet trainer. Later research by Leino and colleagues (1999) further examined the stress response during a flying course and discovered that psychological factors, flight performance and neuroendocrine responses to instrument flight were interrelated with each other, suggesting that understanding the stress response using neuroendocrine and psychological indicators may lead to better flight safety. Understanding the stress response within the context of safe performance is vital to military air flight and potentially to other "high-stress" occupations such as nursing.

Extreme military training. Stress research in military training settings other than flight training have ranged from basic training to austere endurance and survival Army ranger training that included strenuous physical exercise, sleep deprivation, and exposure to extreme environmental conditions. Just as in flight training, understanding the stress response during survival and endurance training provides valuable information about stress

tolerance that can inform stress research in the combat nursing setting. Research focusing on basic recruit training and field training exercises over time has revealed significant differences between stress responses via psychological and hormonal changes. For example, Clow and colleagues (2006) found that recruits may not be willing to reveal honest self-assessments in a competitive training situation. They studied salivary cortisol concentrations as well as self-rated psychological assessments of stress, arousal and fatigue in healthy army recruits at four time points during an 11-week physical training course (n = 12). Although they found cortisol levels were sensitive to the middle time points during the training course, the self-rated assessments of perceived stress remained the same throughout the training course.

Austere and physically demanding training conditions are intended to simulate combat conditions and, as such, provide valuable information about the capacity to complete the military mission safely without injury or incapacitation such as illness. The intensity and duration of physically demanding training reveals differences in the stress response. For example, the effects of exercise and rest on the stress response over time are well illustrated in a study by Kyrolainen and colleagues (2008). They showed that lower levels of energy deficit in later phases of the training allowed for recovery from deficits observed in an earlier training phase. Other researchers (Makras et al., 2005), however, found no significant relationship between immunological and hormonal status over time during military training that incorporated moderate exercise, suggesting that an adaptive immunological process was at work during the training period. These results could have implications for the differences in how military nurses recover from intense clinical

nursing situations in the combat zone, such as the mass casualty or triage situations in comparison to similar non-combat clinical nursing situations in a stateside military medical center emergency department.

Military survival training. Cumulative effects of stress in extremely stressful military training environments, such as in survival training, appear to depend on the training environment. The stress response and its impact on performance are critical to understand when identifying the best methods for safely completing a military mission. Taylor et al. (2007) evaluated a stressful captivity training situation and found that human performance may be negatively affected by the cumulative effects of the stress response. During the stressful captivity situation, overall performance during a high-intensity captivity-related challenge was shown to be inversely related to the DHEAS-cortisol ratio. The study showed poorer performance related to significant increases in cortisol and DHEA when males in a military survival training program moved from a free-living environment to a stressful captivity situation. In two studies, Morgan and colleagues (2000) similarly found significant hormonal responses to the stress of interrogation during Army survival training. Another study (Vaananen et al., 1997) evaluated the hormonal stress effects of extreme physical endurance (a 4-day road march totaling 185 kilometers) on physically active soldiers. Soldiers in this study displayed only *minor* cumulative effects of stress resulting in minor adverse effects on the musculature of soldiers' lower extremities. Nindl and colleagues (2007), however, found *severe* weight loss (greater than or equal to 13% of body mass) when they evaluated the physiological effects of extreme physical military training (an 8-week U.S. Army Ranger training course) and its effects on

strength, power, body composition, and somatotrophic hormones before and after the training course. While military nurses are not typically required to perform their clinical nursing skills within such harsh survival training scenarios, they are trained to perform their nursing skills in field settings that simulate challenging, austere battlefield scenarios that include mass casualty and triage training.

The effects of austere environmental circumstances, perceived psychological stress, and biological factors clearly show that the stress response differs depending on the training situation. Intense flight training, extreme physical training, and survival training exercises that include interrogation procedures are all unique situations that differ in intensity, duration, and realism. Understanding the stress response in training situations may be helpful when considering the stress response under life-threatening combat conditions, although caution should be used in drawing direct comparative conclusions. Despite these contextual differences, longitudinal research could yield important predictive information related to how the stress response evolves over the course of one's military career which may include numerous stateside training situations in addition to frequent deployments to the combat zone.

The Stress Response in Nurses

The nursing profession can be stressful not only because of its personal caregiving component, but also because it often involves rotating shifts, risk of workplace injury such as from needlestick injuries or low back injuries, and even patient and healthcare worker violence. For example, Kobayashi and colleagues (1997) measured physical activity level, mood states, and neuroendocrine responses in nurses on different shifts and found that

nurses experienced lower cortisol and natural killer cell activity levels during the night shift, indicating that the night shift was particularly stressful. McVicar (2003) included literature from 1985 to 2003 in a literature review of nurses' perceptions of workplace stress. He found that workload, leadership/management style, professional conflict and the emotional cost of caring have been the main sources of distress for nurses but that the magnitude of the impact of these stressors differ between studies. McVicar (2003) acknowledges that gaps in understanding workplace stress remain, including how stress differs between practice areas, the lack of predictive power of workplace stress assessment tools, and how personal and workplace factors interact.

Stress and Nursing in Civilian Settings

While the continuous threat of mortar and rocket attacks is certainly a unique stressor for the deployed military nurse in the combat arenas of Iraq and Afghanistan, the typical metropolitan medical center emergency department today has been referred to as a *war zone* due to the traumatic injuries it receives that include gunshot wounds and motor vehicle crashes. Recent studies in civilian work settings reveal differences in the stress response in nurses depending on the job setting and circumstances. One of the more comprehensive stress research studies of nurses (Yang et al. 2001) compared stress between emergency department (ED, n = 23) and general ward (GW, n = 50) nurses in a general hospital. ED nurses perceived their jobs as more stressful when compared with GW nurses when they examined self-perceived work stress along with salivary cortisol levels. Battles (2007) administered demographic and post-traumatic self-report questionnaires to registered nurses (n = 21) in an emergency department approximately 40

miles north of New Orleans. Initial pilot study findings revealed that 20% of nurses in a New Orleans metropolitan area emergency department had PTSD symptoms during and immediately after Hurricane Katrina.

The stress response has also been explored among professional health care providers in the same settings. Ben-Ezra, Palgi, and Essar (2007) noted a difference in stress symptoms between nurses and physicians in a civilian hospital in Israel that came under hostile fire. Military and civilian staff (n = 80) exposed to missile attacks and war casualties were assessed for PTSD symptoms a month after the last days of the war between Lebanon and Israel. Nurses were five times more likely than physicians to experience clinically significant symptoms of posttraumatic stress. However, Fischer et al. (2000) examined the stress response as measured by cortisol fluctuations in neonatal and pediatric critical care staff in civilian critical care situations and found no differences between nurses and physicians working in this setting.

Stress, Nursing and Gender

Gender may also contribute to differences in the stress response in nursing. Fewer men are represented in the profession of registered nursing. Overall, in the U.S., 5.7 % of registered nurses (RNs) are men (U.S. Department of Health and Human Services, 2004) while 35% of RNs in the U.S. Army Nurse Corps (2006) are men. It is not surprising then that the effects of the menstrual cycle on stress in nurses have been evaluated. Davydov, Shapiro and Goldstein (2005) examined women's mood responsiveness in 203 nurses on work days and days off during different phases of the menstrual cycle. Measuring daytime and nighttime hormonal responses along with perceived stress and tiredness, they found

that the menstrual cycle phase was associated with mood differences and that high daytime hormonal responses were associated with higher ratings of stress and tiredness and lower ratings of being happy. In a sample of 315 nurses, Deane, Chummun, and Prashad, (2002) examined gender differences in the stress response. They showed that hormone replacement therapy in women was related to reductions in the hormonal stress response (as measured by urinary cortisol, adrenaline and noradrenaline levels) and thus may have benefit in reducing the level of stress-related illnesses.

Stress and Military Nursing in Vietnam

Like professional nursing in a civilian context, professional nursing within the military context also relates to job dissatisfaction, staff turnover, and nursing shortages. The dramatic difference between the civilian professional nurse and the professional *military* nurse, however, lies in the fact that the military nurse will likely be deployed to a combat zone to deliver patient care soon after her/his initial military nurse officer coursework is completed. While nurses' work is stressful in any healthcare facility, military or civilian, functioning under the continuous threat of hostile fire adds an entirely new dimension to providing patient care. While there is significant data that describe the nature of a nurse's stress in the workplace, a relatively small amount of data describe the stress response and its outcomes in the military nurse.

Studies of stress and readjustment in military nursing in the combat zone have been limited to descriptive, retrospective studies of the stress response of military nurses serving in Vietnam and their personal strategies in dealing with the hardships they faced while deployed in Vietnam (Baker, Menard, & Johns, 1989; Norman, 1988; Scannell-Desch,

2000). The effects of exposure to combat have been shown to have psychological and biological consequences including PTSD, depression, and anxiety, as well as other poor health outcomes, both acute and chronic. Carson et al., (2000) examined Vietnam nurse veterans with and without PTSD to determine whether witnessing death and injury via imagery produced different physiological responses between the two groups of nurse veterans. Scripts describing personal traumatic military nursing events, standard military nursing events, and other life events were tape recorded and played back to the participants and physiological data were recorded. Vietnam nurses with PTSD had significantly higher heart rates, skin conductance, and facial muscle responses than did Vietnam nurses without PTSD, suggesting that the experience of witnessing death and serious wounds could be associated with PTSD.

Burnout has been studied in military nurses with a focus on personal characteristics, such as hardiness, and their relationship to stress. DePew and colleagues (1999) studied 49 nurses in seven special care units in a military medical center to determine whether hardiness predicted burnout and whether hardiness buffered the effects of nursing stress on burnout. Results showed that hardiness accounted for 35% of burnout variance and that adding stress to the regression model had no effect. This suggests that hardiness may not buffer the stress-burnout relationship. Using job-stress and burnout surveys in addition to interviews and demographic information, Van Wijk (1997) also studied burnout in a sample of South African military nurses and found that such factors as age (very young and older nurses), lack of supervisory support and service in isolated geographic areas were associated with higher experiences of burnout reported by nurses.

Characteristics of nurses, such as combat exposure, hardiness, practice setting, practice specialty, and gender each help to explain the stress response of nurses. While particular aspects of the workplace can be similar, such as the type of specialty unit within which the nurse practices and the personal context the nurse brings to that setting may also be important. While similarities exist between military nursing in a combat zone and the potential threat of harm due to violence in the civilian emergency department, the contexts are very different. The military nurse does not have the luxury of *returning to normal* after her/his shift is over because the constant threat of personal harm continues to exist and can thus have long-lasting physical and psychological consequences. Understanding the stress response in various non-combat nursing contexts, however, is useful baseline information against which future combat nursing stress research findings can be compared.

Conclusion

Stress in military nursing, just as in the military and in nursing overall, can dramatically affect job performance in life and death situations and is of great concern to military leadership. The successful military health care mission means completing the mission with the highest possible quality outcome for the patient as well as with the safest outcome for the military member performing the mission. While there is retrospective research examining the stress response from the Vietnam and Gulf War eras, prospective correlational research in military nurses is lacking. Such prospective data gleaned from today's military nurses serving in Iraq and Afghanistan could yield critical predictive information that could show how the stress response changes over time and which

strategies are most beneficial in improving coping strategies, improving health outcomes and improving the retention rates of a highly trained military nurse workforce.

The purpose of this literature review was to present a review of the stress response in military nursing. Although there has been some research related to the physical and psychological outcomes of the stress response in military nurses from the Vietnam era, there is no known prospective research on these outcomes as they relate to the stress response in military nurses today who have served in combat zones. Exploring the stress response in military nursing training settings early in military nurses' careers could provide useful baseline information about stressors and the stress response that could be compared later to post-training practice settings in stateside military nursing settings and in combat nursing settings. Areas for future research could include whether military training experiences of stress predict the stress response in a combat zone. Longitudinal research could yield important predictive information related to how the stress response evolves over the course of one's military career which may include frequent deployments to the combat zone. Understanding how stressful experiences change as military nurses advance in their careers could not only enhance military strategies aimed at retaining highly trained military nurses when they are most valuable, but more importantly, could prevent poor physical and psychological health outcomes resulting from military service as a nurse in the combat zone.

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CHAPTER 3 Exploring the Stress Response in New Army Nurses

Exploring the Stress Response in New Army Nurses

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Background

Effects of exposure to combat have been shown to have psychological consequences for military personnel, including post traumatic stress disorder (PTSD), depression, and anxiety (Kaylor, King, & King, 1987; Kulka et al., 1990; Erickson et al, 2001; and Wolfe, Schnurr, & Brown, 1994). In April, 2008, five years after the start of the war in Iraq, RAND Corporation (Territanielian & Jaycox, 2008), a nonprofit research organization, reported that nearly 20 % (approximately 300,000) of military service members who have returned from Iraq and Afghanistan report symptoms of PTSD or major depression costing the nation as much as $6.2 billion (direct medical care and costs for lost productivity and suicide) in the two years following deployment. While overall stress in military personnel has been studied, stress related to military nursing in the combat zone has been limited to retrospective studies of military nurses who served in Vietnam. That research revealed difficulty coping with stressful situations, experience of post-traumatic stress symptoms and the development of personal strategies in dealing with the hardships experienced in combat nursing (Baker, Menard, & Johns, 1989; Norman, 1988; Scannell-Desch, 2000). There are no data that identify baseline patterns of the stress response, which may relate to the later development of post traumatic stress symptoms, depression or anxiety in military nurses. Further, there is no known research on the relationships between biological stress responses, life experiences and perceived stress in military nurses. Therefore the purpose of this study was to explore the relationships

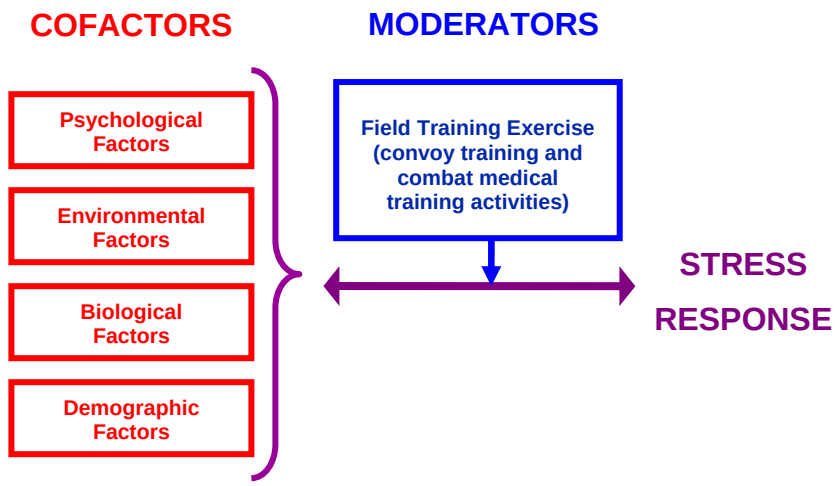
among psychological, environmental, biological and demographic factors of stress in new Army nurses.

In their classic definition of stress, Lazarus and Folkman (1984) identify psychological stress as a "particular relationship between the person and the environment that is appraised by the person as taxing or exceeding his or her resources and endangering his or her well-being" (p. 19). However, evaluating different approaches to understanding the stress response could provide a more comprehensive view of the stress response. Cohen, Kessler, and Gordon (1997) view the stress response as "a process in which environmental demands tax or exceed the adaptive capacity of an organism, resulting in psychological and biological changes that may place persons at risk for disease" (p. 3). This more comprehensive approach to understanding the stress response provides a solid framework for understanding the stress process. Therefore, the current study used the Cohen, et al. framework to understand the stress response in new Army nurses. The stress model depicted in Figure 1 is an adaptation of that framework. Cofactors in this model include psychological, environmental, biological and demographic factors of stress and were evaluated in this study of new Army nurses during their attendance at the Army Medical Department's Officer Basic Leadership Course (OBLC).

Nearly all new Army nurses begin their Army Nurse Corps officer careers in the OBLC. This training venue includes simulated combat-related scenarios such as nuclear, chemical and biological defense; patient evacuation; land navigation; communications; weapons training and other soldier skills that Army nurses can expect to encounter during their careers and, therefore, this training may be a stressful experience. In this study,

specific events during the course that may moderate the stress response included convoy training and combat medical training, both contained in the field training exercise (FTX) portion of the course. Using a descriptive prospective, correlational, repeated measures design, this study provides a description of the baseline relationships among psychological, environmental, biological and demographic factors of stress in new Army nurses during attendance at the 8-week OBLC. The OBLC is an appropriate venue in which to evaluate these baseline factors of stress because, although each course attendee brings a unique life context to OLC, they all have one thing in common: they are new Army nurses.

Figure 1. Research model of the stress response in new Army nurses.



Specifically, this study examined, within a sample of new Army nurses, the relationships among selected psychological, environmental, biological and demographic factors related to stress during attendance at the eight-week OBLC. The OBLC is an appropriate venue in which to evaluate these baseline factors of stress because, although

each course attendee brings a unique life context to OBLC, they all have one thing in common: they are new Army nurses.

Information about the relationship among stress factors may assist military nursing leadership in understanding stress in Army nurses at the beginning of their Army nursing careers as well as throughout their military careers. It may enlighten military nursing leadership with how the stress response contributes to the cumulative effects of stress. Understanding the relationship among stress factors ultimately may be beneficial in designing interventions to decrease the physical and psychological cumulative effects of stress in military nurses so that they can not only perform vital nursing care skills in order to save lives on the battlefield, but to live healthy lives into the future.

Method

Setting

The study setting was the Army Medical Department's (AMEDD's) OBLC at Fort Sam Houston, San Antonio, Texas. This 8-week course focuses on leadership training, the fundamentals of AMEDD health service support, Army administrative and operational overviews, and fundamental survival skills. It includes didactic and clinical skills training in the classroom as well as a 3-week field training exercise (FTX) at Camp Bullis that focuses on individual, collective team, and medical training.

Participants

A convenience sample of 33 active duty Army Nurse Corps officers were recruited to participate in the study during their attendance at either of two 8-week increments of OBLC, between October 2008 and March 2009. All OBLC Army nurses were invited to

participate in the study. There were no exclusion criteria. Of 149 OBLC Army nurses in the October, 2008 class, 19 (12.8%) were enrolled in the study, while in the January 2009 class of 59 Army nurses, 14 (23.7%) were enrolled.

Procedure

A variety of psychological, environmental, biological and demographic factors of stress were measured in this study (Figure 1). Moderators of the stress response included potentially stressful events during the 3-week FTX which included convoy training and the combat medical field training activities. Categories of cofactors, specific concepts and their measures are summarized in Table 1.

Table 1. Proposed factors of stress in new Army nurses.

Cofactors:	Specific concepts:	As measured in this study:
Psychological factors	Unpredictability, lack of control, burden overload, and stressful life circumstances Intrusive, avoidant and hyperarousal symptoms	Perceived Stress Scale Impact of Event Scale – Revised
Environmental factors	Stressful life events	Life Experiences Survey
Biological factor	Hypothalamic-pituitary-adrenal (HPA) response	Salivary cortisol
Demographic factors	Gender, age, race/ethnicity, professional nursing experience and deployment experience	Demographic questionnaire

Psychological factors. Psychological factors in this study include perceived stress and the psychological response to traumatic stressors. The two measures used to evaluate these psychological factors were the Perceived Stress Scale (PSS; Cohen; 1983, 1997, 2000) and the Impact of Event Scale – Revised (IES-R; Weiss & Marmar, 1997). The PSS was completed by study participants during OBLC to measure the degree to which events

in the individual's life over the previous month were perceived as stressful. The IES-R measured how frequently difficulties specified in the scale had been distressing for the individual in the previous week with respect to the identified potentially stressful event.

The PSS, a self-report questionnaire, assesses the domains of unpredictability, lack of control, burden overload, and stressful life circumstances. It is comprised of 14 items on a 5-point scale (0 = Never to 4 = Very often) and measures the degree to which events in the individual's life over the previous month were perceived as stressful. It is a valid and reliable instrument across diverse populations (Cohen; 1983, 1997, 2000) including two college student samples (Cronbach's alpha of 0.84, *N* = 332 and 114) and among working adults volunteering for a smoking cessation intervention (Cronbach's alpha of 0.86, *N* = 64). Each item in the PSS begins with the phrase, *In the last month, how often have you …?*

The IES-R is a self-report questionnaire that assesses the psychological response to traumatic stressors or stressful life events using intrusion, avoidance, and hyperarousal subscales. It is comprised of 22 items on a 5-point scale (ranging from 0 = "Not at all" to 4 = "Extremely") and measures how frequently each of 22 difficulties identified in the scale has been distressing for the individual in the past 7 days with respect to the specified potentially stressful event. The original 15-item IES is a valid and reliable instrument with good to high internal consistency for subscale scores (Horowitz, Wilner & Alvarez; 1979, 2000). Cronbach's alpha ranged from 0.79 to 0.92 for the intrusion subscale and from 0.73 to 0.91 for the avoidance subscale in previous studies. Internal consistency of the three subscales in the IES-R is very high (Intrusion alpha = 0.87 - 0.91, Avoidance alpha = 0.84

- 0.86, and Hyperarousal alpha = 0.79 - 0.90) using samples of Interstate-880 freeway collapse victims and controls (*N* = 429) as well as samples of hundreds of Northridge earthquake victims (*N* = 197) in separate studies. Test-retest reliability ranged from 0.51 to 0.59 for the freeway collapse sample and from .89 to .94 for the earthquake sample. The authors attribute the higher coefficients of the earthquake sample to the shorter interval between assessments and the greater recency of the traumatic event (Weiss & Marmar, 1997). The three subscales show a high degree of intercorrelation (r = 0.52 to 0.87; Creamer, Bell & Failla, 2003).

Environmental factors. Environmental factors provide information about exposure to and the impact of stressful life events that can represent significant changes in one's life. Carson et al., (2000) examined Vietnam nurse veterans with and without PTSD who witnessed decades earlier the outcomes of traumatic wartime injuries in order to determine whether witnessing death and injury via imagery could produce different physiological responses between the two groups of nurse veterans. Vietnam nurses with PTSD had significantly higher heart rates, skin conductance, and facial muscle responses than Vietnam nurses without PTSD suggesting that the experience of witnessing death and serious wounds could be associated with PTSD.

The Life Experiences Survey (LES; Sarason, Johnson & Siegel, 1978) is a self-report questionnaire that rates the desirability or undesirability of life experiences that typically occur in the general population, allowing for the relative contributions made by both negative and positive life changes in the previous 12 months. It is comprised of 57-items on a 7-point scale (-3 to +3) that reflects an impact range of the event in the

individual's life (extremely negative impact to extremely positive). In addition, there are three open-ended, fill-in spaces to add events not included among the 57 items on the survey. In a study of undergraduate university students (N = 345), Sarason et al. (1978) documented a moderate level of reliability especially for test-retest of negative change scores (0.56-0.88). However, test-retest for positive change scores and total changes scores were not as reliable (0.19-0.53 and 0.63-0.64 respectively (Sarason; 1978, 2000).

Biological factors. Biological factors of stress have been studied for decades. Salivary cortisol is a marker for stress based on the hypothalamic-pituitary-adrenal (HPA) response (Gozansky et al., 2005). Stress activates the hypothalamic-pituitary-adrenocortical (HPA) and sympathetic-adrenomedullary (SAM) systems contributing to the dysregulation of these systems and the development of disease processes such as depression and chronic migraines (Banki et al., 1992; Nemeroff et al., 1984; Patacchioli et al., 2006.) HPA function was of particular interest in this study because there is a paucity of research that has explored biological responses to stress in military nurses and its relationships with perceived stress and other potential cofactors. Although Yang et al. (2001, 2002), found higher stress in emergency department nurses compared to general ward nurses when they examined salivary IgA, lysozyme, and cortisol levels, there is no known research on the relationships among biological factors of stress and perceived stress in military nurses.

As an indicator of HPA axis function, cortisol has well-established circadian rhythms (Kronfol et al., 1997; Pfohl, Sherman et al., 1985). Although salivary cortisol levels are significantly less concentrated than plasma cortisol levels, salivary cortisol is a

reliable measure of stress reflecting the same circadian pattern as plasma cortisol whereby peak cortisol levels are typically found in the early morning hours 30 minutes after awakening (Pruessner et al., 1997). Salivary cortisol is preferable to serum cortisol because of the ease of collection; it is less invasive especially for repeated measurements in a naturalistic setting over an extended period of time (Gozansky et al., 2005).

For this study, salivary cortisol using the filter paper collection method was used to collect saliva over an extended period of time. This method of collection has been shown to be a particularly straightforward, non-invasive, minimally demanding and valid method of saliva collection and, therefore, a feasible method for saliva collection in military field training settings. Additionally, saliva samples collected on filter paper can be dried and stored without a need for refrigeration before laboratory assaying (Neu et al., 2007).

In order to validate the filter paper method in our laboratory, saliva collection and sample extraction procedures were verified using saliva simultaneously collected by salivette, passive drool, and the filter paper methods. With the filter paper samples saturated beyond a pre-marked line on the filters, 4.5-centimeter sections of saturated filter paper were used for the assay validation tests. Following the procedures used by Laudenslager's laboratory (Neu et al., 2007), filters were eluted using 500 microliters of assay buffer and shaking at room temperature for 24 hours. Using the sample volume of 25 microliters as called for in the Salimetrics® cortisol kit, salivette and passive drool samples were found to be consistent, but the filter paper samples were approximately half of these values. After experimenting with varying amounts of filter paper sample, a 50-microliter

sample volume was found to be consistent with the salivette and passive drool samples in the Center for Biobehavioral Clinical Research laboratory.

Demographic factors. Demographic factors (gender, age, race/ethnicity, registered nurse experience and deployment experience) may provide valuable information about the differences in perceived stress levels in new Army nurses. Demographic differences as well as prior nursing and/or military experience may be related to differences in stress in new Army nurses. For example, in a study of Gulf War veterans (Vogt et al., 2005), women's experiences of more interpersonal stressors had a greater effect on their mental health than did men's experiences. Demographic information for the current study was collected on study admission using a demographic questionnaire.

Study Recruitment

Following Institutional Review Board approval, recruitment flyers were posted on OBLC informational bulletin boards at the AMEDD Center and School during the first week of each OBLC (October, 2008 and January, 2009) and brief study information sessions were provided to the OBLC Army nurses as a group by the principal investigator during the first week of OBLC. The study information sessions included data collection information as well as salivary cortisol collection instructions. Participants had up to three days to decide whether or not to participate in the research study. If nurses decided to participate in the study, they completed the informed consent documents.

Data Collection

Data collection occurred during three time points during each OBLC class (Table 2). Upon completing informed consent documents, participants subsequently completed

research materials for the first time point of data collection (baseline). Research materials included the Perceived Stress Scales, the Impact of Event Scales-Revised, the Life Experiences Survey, salivary cortisol collections materials, the demographic questionnaire, instructions for each data collection time point and return envelopes. Since data collection was conducted over three time points throughout the 8-week OBLC, brief reminders were coordinated with OBLC leadership and verbally presented to participants by the principal investigator before data collection time points in order to encourage continued study participation. Additionally, the participants were encouraged to continue to participate in the study even if a previous survey or saliva sample had been missed.

Table 2: Data collection schedule during an 8-week OBLC increment.

TIME POINT VARIABLE	Beginning of OBLC	FTX (convoy and combat medical training activities)	End of OBLC
Perceived Stress Scale (PSS)[1]	**X**	___	**X**
Impact of Event Scale-Revised (IES-R)[2a-c]	**X**[2a]	**X**[2b]	**X**[2c]
Life Experiences Survey (LES)[3]	**X**	___	___
Salivary Cortisol[4]	**X**	**X**	**X**
Demographic Questionnaire[5]	**X**	___	___

Note:
[1] PSS – To be completed during the first and last weeks of OBLC.
[2a] IES-R – Identified stressful event is "beginning of OBLC"; to be completed at the time of the demographic survey, the LES, the first PSS and first day of salivary cortisol samples.
[2b] IES-R – Identified stressful events are convoy and combat medical training to be completed no later than 7 days after these activities.
[2c] IES-R – Identified stressful event is "end of OBLC"; to be completed at the time of the final PSS and final day of salivary cortisol samples.
[3] LES – To be completed during the first week of OBLC.
[4] Salivary cortisol – Four samples collected per day per time point (30-minutes after rising, mid-day, afternoon, and evening) during the following days: any day during the first week of OBLC, during convoy and combat medical training days during the FTX, and any day during the final week of OBLC.
[5] Demographic questionnaire – To be completed during the first week of OBLC.

Over the 8-week course, stressful events for the IES-R scales were defined as the beginning of OBLC, the FTX, which included convoy and combat medical training activities, and the end of OBLC. Participants were instructed to complete surveys on the

same day the salivary cortisol samples were collected during each of the data collection time points. Participants received verbal and written instructions regarding the salivary cortisol filter paper collection procedure. Saliva collection occurred four times a day for each time point: 30-minutes after awakening, before lunch, afternoon, and at bedtime. The participants were instructed to turn in their saliva samples using the prepared saliva collection folders along with their completed surveys using the return envelopes provided. Participants deposited their completed research materials at a designated collection point identified by the principal investigator at the time of the informational session.

Data Analysis

The number and frequency for each demographic characteristic was computed and is presented in Table 3. To examine baseline comparability of the sample for the PSS scores, IES-R scores, LES scores, and salivary cortisol level; means (and standard deviations) were compared by gender, deployment experience and RN experience using a two-sample *t*-test. In order to describe the relationships among the major study variables, Pearson correlation coefficients were calculated for each study variable pairing. The normality assumptions were checked and confirmed for the major study variables.

A simple repeated measures random effects model was used to detect differences in means for the PSS scores, IES-R scores and salivary cortisol levels over time. The LES score was included in each of the three models as a covariate. Statistics were computed using JMP™ software (version 8.0, SAS institute, Cary, North Carolina). The alpha level was established at 0.05.

Results

This study examined the relationships among psychological, environmental, biological and demographic factors related to stress within a sample of new Army nurses during their attendance at the 8-week OBLC. Data collection occurred during three time points during the training period: during the first week of OBLC, during the FTX, and during the final week of OBLC. The FTX included convoy training and combat medical training activities which were thought to be stressful experiences in this study. Only the first-morning saliva samples during each time point were used for analyses because of participants' limited completion of saliva collections during the reminder of the day.

Participants

Of 33 participants enrolled in the study, only 12 completed data collection materials for all time points. However, a total of 33 individuals completed some or all of the data collection materials at the beginning of OBLC; 18 participants completed some or all of the data collection materials during the FTX and 16 participants completed some or all of the data collection materials at the end of OBLC. The majority of participants were single, Caucasian females under 30 years of age with no RN experience and no deployment experience. While 79% of participants were female and 21% were males, no significant gender differences were detected with regard to the study variables (Table 3).

Table 3. Demographic characteristics of participants.

Demographic Characteristic	Study Proportion *n* (%)
Gender	
Male	7 (21.2)
Female	26 (78.8)
Age (years)	
20-24	15 (45.5)
25-29	5 (15.2)
30-34	6 (18.2)
35-39	2 (6.1)
40-49	4 (12.1)
50+	1 (3.0)
Race	
Caucasian	23 (69.7)
African American	4 (12.1)
Asian	1 (3.0)
Multiracial	3 (9.1)
Marriage Status	
Single and Never Married	20 (60.6)
Married	10 (30.3)
Divorced	2 (6.1)
Divorced and Widowed	1 (3.0)
Number of Children	
Zero	22 (66.7)
One	8 (24.2)
Two	2 (6.1)
Three or more	1 (3.0)
Deployment Experience	
Yes	5 (15.2)
No	28 (84.8)
RN Experience	
Yes	10 (30.3)
1-10 years	8 (24.2)
11 years or more	2 (6.1)
No	23 (69.7)

Note: Proportion based on 33 study participants at the beginning of OBLC.

Baseline PSS scores, IES-R scores, LES scores, and salivary cortisol levels were compared by gender, deployment experience and RN experience (Table 4). No significant differences were found among the study variables ($p \geq 0.05$).

Table 4. Baseline (beginning of OBLC) means (and standard deviations) demonstrating comparability of study variables.

DEMOGRAPHIC VARIABLE	Gender		Deployment Experience		RN Experience		
STRESS MEASURE	Male *n* = 7	Female *n* = 26	Yes* *n* = 5	No *n* = 28	Yes* *n* = 10	No *n* = 23	Pooled *n* = 33
PSS							
Mean	35.37	38.62	39.60	37.68	40.00	37.09	37.97
S.D.	8.85	8.10	7.20	8.48	6.70	8.79	1.43
IES-R							
Mean	16.00	22.48	16.20	21.96	23.89	19.96	21.06
S.D.	12.19	19.25	14.45	18.64	19.38	17.72	3.18
LES							
Mean	14.29	19.38	21.60	17.71	14.60	19.91	18.30
S.D.	11.91	10.63	13.39	10.61	9.58	11.27	1.90
Salivary Cortisol (µg/dl)							
Mean	0.24	0.23	0.21	0.23	0.25	0.22	0.23
S.D.	0.15	0.14	0.14	0.15	0.14	0.15	0.03

Note: * Deployment experience/Yes = $\geq$ 3months; RN experience/Yes = $\geq$ 1year.

Stress Factor Associations

Two statistically significant correlations were found among study variables (Table 5.) A significant negative correlation was found between salivary cortisol levels during the FTX and the LES score (r = -0.60) and a significant positive correlation was found between salivary cortisol levels during the FTX and the salivary cortisol levels at the beginning of OBLC. All correlations among psychological factor variable pairs (PSS and IES-R scores) were significant.

Table 5. Pairwise correlation matrix of study variables.

VARIABLE	PSS Begin OBLC	PSS End of OBLC	IES Begin OBLC	IES FTX	IES End of OBLC	LES Begin OBLC	Cortisol Begin OBLC	Cortisol FTX
PSS End of OBLC	0.82*	.	.	.	.	.	.	.
IES – R Begin OBLC	0.54*	0.58*	.	.	.	.	.	.
IES – R FTX	0.49*	0.61*	0.86*	.	.	.	.	.
IES – R End of OBLC	0.54*	0.71*	0.84*	0.83*	.	.	.	.
LES Begin OBLC	0.20	-0.17	0.25	0.31	0.29	.	.	.
Cortisol Begin OBLC	0.23	0.09	0.22	0.23	-0.21	-0.04	.	.
Cortisol FTX	0.15	-0.11	-0.01	-0.02	-0.36	-0.60*	0.57*	.
Cortisol End of OBLC	0.22	0.04	-0.16	-0.09	-0.09	-0.09	0.20	0.22

Note: * $p \leq 0.05$.

Repeated Measures Models of Stress

A simple (single-group) repeated measures analysis of the psychological (PSS and IES-R scores) and biological (salivary cortisol) factors was conducted using the environmental factor (LES score) as a covariate. The adjusted (or least square) means from the repeated measures analysis are presented in Table 6. While the PSS scores and salivary cortisol levels did not change significantly over time, the IES-R score did change significantly over time ($p = 0.001$). The environmental factor (LES score) was not significant as a covariate in any of the three models.

Table 6. Adjusted means from the simple (single-group) repeated measures analysis for study variables using LES as a covariate.

TIME POINT VARIABLE	Beginning of OBLC	FTX	End of OBLC	p-value
PSS *n* Mean (SE)	33 38.02 (1.52)	—	15 36.00 (1.86)	0.188
IES-R *n* Mean (SE)	32 21.02 (2.97)	17 11.21 (3.48)	16 22.23 (3.52)	0.001
Salivary Cortisol (µg/dl) *n* Mean (SE)	29 0.23 (0.02)	18 0.24 (0.03)	14 0.18 (0.03)	0.290

Discussion

An adaptation of the Cohen stress framework guided this study in examining the stress response in a sample of new Army nurses attending the OBLC. This broad approach to exploring the stress response is particularly suited for nurses embarking on careers as

military nurse officers because it offers baseline information about stress that can be used in exploring stress later in military nurses' careers. Using a descriptive prospective, correlational, repeated measures design, this is the first known study to explore psychological, environmental, biological and demographic factors of stress within a military nursing population.

Participants

The sample was similar to the Army Nurse Corps' overall representation for gender and race. Nurses who make up the U.S. Army Nurse Corps are typically 65% female, 65% Caucasian, 19% African American and 11% of other races (U.S. Army Nurse Corps, 2006). Unlike the overall U.S. representation of men in nursing (5.7%; U.S. Department of Health and Human Services, 2004), men represent over one-third of the U.S. Army Nurse Corps (U.S. Army Office of the Surgeon General, 2003). In addition, this sample was comprised of participants who had minimal deployment and RN experience as would be expected in the Officer Basic Leadership Course.

Stress Factor Changes Over Time

Of the factors examined over time in this study, one psychological factor, the impact of stressful events, decreased significantly over time while the biological factor reflected by salivary cortisol levels and the psychological factor of perceived stress did not change significantly over time. Perceived stress and the psychological response to stressful life events have been studied in other military training settings. Clow and colleagues (2006) explored the differences between psychological and biological stress responses over time in healthy army recruits during basic training and field training

exercises. They evaluated salivary cortisol levels as well as self-rated psychological assessments of stress in army recruits (n = 12) at three time points during an 11-week physical training course. Similar to their findings, the current study reveals differences in psychological and biological responses to stress; but specific results of the current study differ subtly. While Clow et al. (2006) found cortisol levels were sensitive to stressful time points during the training course, the self-rated assessments of stress remained the same throughout the training course. In the current study, however, while salivary cortisol levels showed no significant changes over time, the psychological response to stressors, as reflected by the IES-R score during the FTX, decreased significantly. Clow et al., however, used different measures of psychological stress and the demographic characteristics of their sample also differed from the current study. The Clow et al. study used the Cox-Mackay Stress Arousal Checklist, a two-dimensional scale measuring stress (general well-being in response to the external environment) and arousal (wakefulness representing autonomic activity); the current study used the Impact of Event Scale – Revised (IES-R) which assesses the psychological response to stressful life events using intrusion, avoidance, and hyperarousal subscales that evaluate distress with respect to the identified specific potentially stressful event (the FTX). Thus, results may have differed because the two scales detect stress differently.

In addition, Clow et al. studied British enlisted military recruits ranging from 18 to 24 years of age who were primarily males (13 males and 7 females); while the current study consisted of an older, primarily female sample. It is also likely that Clow et al. included a more academically and professionally diverse sample, whereas, all participants

in the current study possessed the bachelor's degree in nursing, which also may have contributed to the differences in the psychological response to stress between the two studies.

In the current study, it is not immediately clear why the IES-R score was significantly decreased during the FTX. It is possible that fewer administrative demands (testing, presentations, etc.) were required of the participants as they were in a field setting where there was no access to computers or telephones. The classroom setting may have been perceived as a more stressful experience related to the administrative demands placed on participants. Or perhaps the camaraderie that is sometimes felt in the field setting contributed to a less stressful experience.

Gender Differences

While no significant gender differences were detected in the current study, these findings, nevertheless, provide baseline information about stress factors in military nurses. Retrospective research, on the other hand, shows that gender does contribute to differences in the health outcomes in women in military service. Research has shown that certain cancers, for example, are related to women's wartime service. Using Veterans Administration personnel roster data between 1965 and 1973, researchers (Dalager, Kang & Thomas, 1995; Thomas, Kang & Dalager, 1991) compared military women's service in Vietnam with military women who did not serve in or near a combat zone. They found that the death rate from pancreatic and uterine cancers was more than double for women veterans who served in Vietnam. Other researchers (Breslau, 2002) used a representative sample in a metropolitan area to interview over 2,000 subjects, 18-45 years of age, in

order to assess individuals' risk of PTSD and experience of traumatic events. Breslau found that the PTSD risk following traumatic events was double for women primarily due to women's increased exposure to personal assaultive violence. Additionally, the duration of PTSD for women was longer than for men. This is particularly relevant for the military community in light of a recently published Department of Defense report on sexual assault in the military (2009). Of the 6.8% of women and 1% of men who reported unwanted sexual contact, only one fifth of them reported the matter to an authority.

Conclusion

This descriptive prospective, correlational repeated measures study provides information about the relationships among psychological, environmental, biological and demographic factors of stress in new Army nurses as they begin their Army nursing careers. The unique baseline findings in this study may provide a springboard for further studies in stress, particularly with military nurses who will eventually be deployed and experience a variety of stressful events. How they respond to those events may be related to the responses to stress reported here.

Limitations to this study included the potential variability of cortisol collection and self-selection of the study sample. While salivary cortisol collection instructions specified times for collection (for example, 30 minutes after awaking), there was no study verification procedure to ensure compliance. Only one first-morning saliva sample was requested of participants which potentially decreased the accuracy of a true peak cortisol level. Serial first-morning cortisol collections (upon awaking, 15 minutes after awaking,

30 minutes after awaking, 45 minutes after awaking and 60 minutes after awaking) could have increased accuracy of peak cortisol levels. An additional study limitation included variability among study participants completing their study materials. Participants were asked to complete their materials, for example, on "any day during your FIRST week of OBLC at your convenience" with the added request to "complete all the surveys on the same day that you collect your saliva samples". While this provided flexibility for study participants, it may have added to variabilityduring data collection and in study results since not all participants completed their study materials on the same day. In addition, if participants completed their materials on a weekend (a leisure day) rather than a weekday (a work day), study results may have been affected (Kunz-Ebrecht et al., 2004.) The limitation of participant self-selection could also have affected study results. Individuals who did not feel as *stressed* by OBLC may have elected to participate in the study; whereas, *stressed* individuals may have chosen not to participate due to the addition of *burdensome* materials to complete during OBLC.

In the future, longitudinal studies of the stress response in military nurses serving in and out of combat zones may be beneficial in order to identify ways to reduce the negative outcomes of these experiences. Certainly in the present environment, frequent, stressful deployments cannot be avoided, but improved knowledge of how the stress response evolves over time may yield important information to improve the retention rates of a highly trained military nurse workforce and military nurses' long-term health.

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Appendix

VCU RESEARCH PLAN TEMPLATE

Use of this template is required to provide your VCU Research Plan to the IRB. Your responses should be written in terms for the non-scientist to understand. If a Sponsor's protocol exists, the Research Plan may reference the Sponsor's protocol and cite appropriate page numbers. NOTE: If the Sponsor's protocol does not provide all of the information required in each Section Heading, then this information must be provided in the Plan. It is NOT acceptable to reference a research funding proposal.

ALL Sections of the Human Subjects Instructions must be completed with the exception of the Section entitled "Special Consent Provisions." Complete that Section if applicable. When other Sections are not applicable, list the Section Heading and indicate "N/A."

NOTE: The Research Plan is required with ALL submissions and MUST follow the template, and include version number or date, and page numbers.

DO NOT DELETE SECTION HEADINGS OR THE INSTRUCTIONS.

I. TITLE

EXPLORING THE STRESS RESPONSE IN NEW ARMY NURSES

II. STAFFING

A. In the table below (add additional rows as needed), indicate: (1) key project personnel including the principal investigator and individuals from other institutions, (2) their qualifications, and (3) a brief description of their responsibilities.

NAME OF INDIVIDUAL	QUALIFICATIONS	RESPONSIBILITIES
Mary Jo Grap	PhD, RN, FAAN; Professor, School of Nursing	Faculty Advisor; Principal Investigator
Laureen Otto	MS, RN; Doctoral Candidate, School of Nursing	Doctoral Candidate; Student Investigator
Nancy McCain	DSN, RN, FAAN; Professor; Director, Center for Biobehavioral Clinical Research, School of Nursing	Dissertation Committee Member; Laboratory Consultant
R. K. Elswick	PhD; Associate Professor, Department of Biostatistics	Dissertation Committee Member; Study Biostatistics Consultant
COL Kathleen Dunnam	PhD, RN, CNM; Chief, Dept. of Nursing Science, Army Medical Department Center & School, Fort Sam Houston, San Antonio, Texas	Study Consultant

B. Describe the process that you will use to ensure that all persons assisting with the research are adequately informed about the protocol and their research-related duties and functions.

The principal investigator and student investigator will meet approximately weekly throughout the proposal and dissertation process to discuss study processes. Monthly communication between each investigator will ensure that they are adequately informed about the protocol and each investigator's study-related duties and functions.

III. CONFLICT OF INTEREST

Describe how the principal investigator and sub/co-investigators might benefit from the subject's participation in this project or completion of the project in general. Do not describe (1) academic recognition such as publications or (2) grant or contract based support of VCU salary commensurate with the professional effort required for the conduct of

the project

The principal investigator and student investigator in this study will not benefit financially from subjects' participation in the study or from completion of this project.

IV. RESOURCES

Briefly describe the resources committed to this project including: (1) time available to conduct and complete the research, (2) facilities where you will conduct the research, (3 availability of medical or psychological resources that participants might require as a consequence of the research (if applicable), and (4) financial support.

The student investigator is conducting this study as her doctoral dissertation study and therefore is committed through dissertation hours as required by the university. The study will be conducted at locations convenient to study participants in the San Antonio, Texas area. All study participants will be active duty military personnel and, as such, will have access to military inpatient and outpatient medical and psychological resources as needed through the military health system in San Antonio, Texas (Brooke Army Medical Center.) The student investigator will incur travel expenses which will be privately funded by the student. Laboratory and data analysis expenses will also be privately funded by the student and conducted at the Virginia Commonwealth University's School of Nursing's Center for Biobehavioral Clinical Research.

V. HYPOTHESIS

Briefly state the problem, background, importance of the research, and goals of the proposed project.

There are no hypotheses for this study because it is a descriptive study. The research question guiding this investigation is: What are the relationships among biological, demographic, environmental and psychological factors of stress in new Army nurses? Effects of exposure to combat have been shown to have psychological and biological consequences for military personnel, including PTSD, depression, and anxiety (Kaylor, King, & King, 1987; Kulka, Schlenger, W. E., Fairbank, et. al., 1990; Erickson, Wolfe, King, et. al., 2001; and Wolfe, Schnurr, & Brown, 1994.) While overall stress in military personnel has been studied, stress related to military nursing in the combat zone has been limited to retrospective studies of military nurses who served in Vietnam (Baker, Menard, & Johns, 1989; Norman, 1988; Scannell-Desch, 2000.) There are no data that identify early baseline patterns of the stress response, which may relate to the later development of post traumatic stress symptoms, depression or anxiety in military nurses. Further, there is no known research on the relationships between biological stress responses, life experiences and perceived stress in military nurses. Because there are no studies that describe the relationships among biological, demographic, environmental and psychological factors of stress in military nurses, the goal of this study is to use a descriptive prospective, correlational design with longitudinal measures to explore the relationships among these factors of stress in new Army nurses.

VI. SPECIFIC AIMS

THE SPECIFIC AIM OF THIS STUDY IS TO EXAMINE, WITHIN A SAMPLE OF NEW ARMY NURSES, THE RELATIONSHIPS AMONG SELECTED BIOLOGICAL, DEMOGRAPHIC, ENVIRONMENTAL AND PSYCHOLOGICAL FACTORS RELATED TO STRESS DURING ATTENDANCE AT THE EIGHT-WEEK OFFICER BASIC LEADERSHIP COURSE.

VII. BACKGROUND AND SIGNIFICANCE

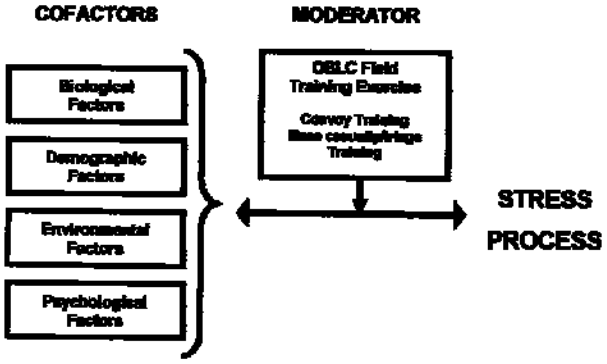
Include information regarding pre-clinical and early human studies. Attach appropriate citations.

The effects of exposure to combat have been shown to have physical and psychological consequences including post traumatic stress disorder (PTSD), depression, and anxiety, as well as other health outcomes, both acute and chronic (Kaylor, King, & King, 1987; Kulka, Schlenger, W. E., Fairbank, et. al., 1990; Erickson, Wolfe, King, et. al., 2001; and Wolfe, Schnurr, & Brown, 1994.) While overall stress in the military has been studied, studies of stress in military nursing in the combat zone, for the most part, have been limited to retrospective studies of military nurses who served in Vietnam (Baker, Menard, & Johns, 1989; Norman, 1988; Scannell-Desch, 2000) that revealed difficulty coping with stressful situations, the experience of post-traumatic stress symptoms, and the development of personal strategies in dealing with the hardships experienced in combat nursing. Recently, stress has been studied in nurses in civilian, non-combat settings (Ben-Ezra, Palgi, & Enav, 2007) where a difference in stress symptoms was noted between nurses and physicians in a civilian hospital in Israel that came under hostile fire; nurses were five times more likely than physicians to experience

clinically significant symptoms of posttraumatic stress. In another study (Battles, 2007), initial pilot study findings revealed that 20% of nurses in a New Orleans metropolitan area emergency department had post-traumatic stress symptoms during and immediately after Hurricane Katrina.

In their classic definition of stress, Lazarus and Folkman (1984) identify psychological stress as a "particular relationship between the person and the environment that is appraised by the person as taxing or exceeding his or her resources and endangering his or her well-being" (p. 19). However, evaluating different approaches to understanding the stress response would provide a comprehensive view of the process. Cohen, Kessler, and Gordon (1997) view the stress response as "a process in which environmental demands tax or exceed the adaptive capacity of an organism, resulting in psychological and biological changes that may place persons at risk for disease" (p. 3). The proposed study is guided by this framework in order to understand the stress process in the new Army nurse. The stress process model in Figure 1 depicts an adaptation of the Cohen, Kessler and Gordon (1997) framework. Cofactors included in this model include biological, demographic, environmental, and psychological factors of stress and will be measured in this study of new Army nurses. The Officer Basic Leadership Course (OBLC) is the venue in which these cofactors will be explored in this study. *Moderators* indirectly contribute to health outcomes and can include confounding variables or covariates. In this model, moderators include potentially stressful events during OBLC including convoy training and mass casualty/triage training. Each category of cofactors is described below. Table 1 lists specific concepts and measures for each cofactor.

Figure 1. Proposed research model of the stress process in new Army nurses.



Biological factors. Biological factors of stress have been studied for decades. Researchers have long known that salivary cortisol is a marker for stress based on the hypothalamic-pituitary-adrenal (HPA) response (Gozansky, Lynn, & Laudenslager, et. al., 2005). Stress is known to activate the hypothalamic-pituitary-adrenocortical (HPA) and sympathetic-adrenomedullary (SAM) systems contributing to the dysregulation of these systems and the development of disease processes such as depression and chronic migraines (Banki, Karmacsi, Bissette, et. al., 1992; Nemeroff, Widerlov, Bissette, et. al., 1984; Putschbidi, Monnazzi, Simeoni, et. al., 2006.) HPA function is of particular interest in this study because there is a paucity of research that explores biological responses to stress in military nurses and its relationships with perceived stress and other potential cofactors. Moreover, research that documents biological function, onset, and course of disease in the same subjects is sorely lacking (Dorna, 2004.) Although Yang, Koh, Ng, et. al. (2001, 2002), found higher stress in emergency department nurses compared to general ward nurses when they examined stress using salivary IgA, lysozyme, and cortisol levels, there is no known research on the relationships among biological factors of stress and perceived stress in military nurses.

Demographic factors. New Army nurses attending the Officer Basic Leadership Course (OBLC), the venue in which most new Army nurses begin their Army nursing careers, understand the likelihood of deployment to a combat zone in today's global threat environment. Each new Army nurse attending OBLC brings with her/him a unique life context of demographic factors ranging from the seasoned combat veteran new to the profession of nursing to the seasoned professional emergency room nurse with no military experience. As potential cofactors, demographic factors in new Army nurses (including age, gender, race/ethnicity, marital status, number of children, years in professional nursing, prior military experience, and prior deployment experience) may provide valuable information about, for example, the

differences in perceived stress levels in new Army nurses. Gender, for example, may contribute to differences in the stress response in military nursing. Fewer men are represented in the profession of registered nursing. Overall, in the U.S., 5.7 % of nurses are men (U.S. Department of Health and Human Services, 2004) and 35% in the U.S. Army Nurse Corps (U.S. Army Nurse Corps, 2006) are men. It is not surprising then that the effects of the menstrual cycle on stress in nurses has been evaluated. Davydov, Shapiro, Goldstein (2005) examined women's mood responsiveness in 203 nurses on work days and days off during different phases of the menstrual cycle. In measuring daytime and nighttime hormonal responses along with perceived stress and tiredness, they found that the menstrual cycle phase was associated with mood differences and that high daytime hormonal responses were associated with higher ratings of stress and tiredness and lower ratings of being happy. In a sample of 315 nurses of both sexes, Deane, Chinnman, & Prashad, (2002) examined gender differences in the stress response. They showed that hormone replacement therapy may reduce the hormonal stress response (as measured by urinary cortisol, adrenaline and noradrenaline levels) and may show benefit in reducing the level of stress-related illnesses.

Environmental factors. Environmental factors provide valuable information about exposure to and the impact of stressful life events that can represent significant changes in one's life. For example, the Life Experiences Survey (LES) developed by Sarason, Johnson, & Siegel (1978), is a self-report questionnaire that gives the study participant the opportunity to rate the desirability or undesirability of different types of potentially stressful life experiences that typically occur in the general population. Environmental factors may reveal differences between Army nurses' impact of life experiences scores which may be related to, for example, military deployment experience. For example, Carson, Paulus, Lasko, et. al., (2000) examined Vietnam nurse veterans with and without PTSD who witnessed decades earlier the outcomes of traumatic wartime injuries in order to determine whether witnessing death and injury via imagery could produce different physiological responses between the two groups of nurse veterans. Vietnam nurses with PTSD had significantly higher heart rates, skin conductance, and facial muscle responses than Vietnam nurses without PTSD suggesting that the experience of witnessing death and serious wounds could be associated with PTSD.

Psychological factors. Psychological factors, such as perceived stress or perceived intrusiveness of a memory, provide descriptive information about the stress process. How perceived stress and intrusive, avoidant and hyperarousal symptoms are related to biological factors can increase our understanding of how the stress process can impact health outcomes. Psychological factors of stress can provide descriptive information about the stress response process. For example, Clow, Edwards & Owen, et. al. (2006) found that military recruits may not have been willing to reveal honest self-assessments in a competitive training situation. They studied salivary cortisol concentrations as well as self-rated psychological assessments of stress, arousal and fatigue in healthy army recruits. Although they found cortisol levels were sensitive to stressful time points during the training course, the self-rated assessments of perceived stress remained the same throughout the training course. Differences in psychological factors may be related to particular demographic factors of new Army nurses.

Table 1. Proposed model factors.

Cofactors:	Specific concepts:	As measured in this study using:
Biological factor	Hypothalamic-pituitary-adrenal (HPA) response	Salivary cortisol
Demographic factors	Gender, age, race/ethnicity, marital status, number of children, years in professional nursing, prior military experience, and prior deployment experience	Demographic questionnaire
Environmental factors	Stressful life events	Life Experiences Survey
Psychological factors	Unpredictability, lack of control, burden overload, and stressful life circumstances Intrusive, avoidant and hyperarousal symptoms	Perceived Stress Scale Impact of Event Scale – *Revised*

The proposed study will provide an initial opportunity to describe baseline relationships among biological, demographic, environmental and psychological factors to better understand the stress response in new Army nurses. Baseline descriptive information about stress in new Army nurses is critical in developing a trajectory of research examining longitudinally the stress experienced by Army nurses throughout their Army nursing careers. Moreover, this study could dramatically impact retention efforts of Army nurses as the Army uses this information to tailor effective

coping and treatment strategies at different critical stress points throughout an Army nurse's career.

As an initial study in this program of research, the purpose of this dissertation research study is to describe baseline relationships among biological, demographic, environmental and psychological factors of stress in new Army nurses as they begin their Army nursing careers. This study will focus on stressful experiences for new Army nurses during the Officer Basic Leadership Course (OBLC), the venue where nearly all new Army nurses begin their Army nursing careers. OBLC is an ideal venue in which to evaluate stress because, although each course attendee brings a unique life context to OBLC, they all have one thing in common: they are new Army nurses. Initial baseline information at this time could reveal unique differences in stress between, for example, those who have and have not previously deployed. Long term, this information could assist military nursing leadership in understanding stress in Army nurses throughout their Army nursing careers. These data could be used as the foundation for interdisciplinary, translational research exploring the effects of coping and treatment interventions to alleviate stress during critical stressful time points for Army nurses throughout their careers and thus could impact retention of Army nurses in the U.S. Army Nurse Corps.

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VIII. Preliminary Progress/Data Report
If available.

OBLC Observation. The student investigator discussed the feasibility of this study with the Chief, Department of Nursing Science; the Deputy Director, Leadership Development Branch, (OBLC); and the OBLC Nurse Track Advisor at the Army Medical Department Center & School. All agreed that this study was feasible. In addition, following an informal observation of OBLC and the field training exercise training days, and following a discussion with dissertation committee members, the principal and student investigators determined that exploring stress in a sample of new Army nurses at OBLC using the following research design is feasible.

IX. Research Method and Design
Include a brief description of the project design including the setting in which the research will be conducted and procedures. If applicable, include a description of procedures being performed already for diagnostic or treatment purposes.

Research Design: The purpose of this dissertation study is to describe baseline relationships among biological, demographic, environmental and psychological factors of stress in new Army nurses as they begin their Army nursing careers. The specific aim of this study is to examine, within a sample of new Army nurses, the relationship among selected demographic, environmental, psychological and biological factors related to stress during attendance at the eight-week Officer Basic Leadership Course (OBLC.) Using a descriptive prospective, correlational research design with longitudinal measures will allow the investigator to describe baseline relationships among biological, demographic, environmental and psychological factors of stress in new Army nurses. Additionally, changes in the biological factor, psychological factors and environmental factor will be described over time.

Research Setting: The study setting will be the Army Medical Department's OBLC at Fort Sam Houston, San Antonio, Texas. This study setting will allow the student investigator to focus on potentially stressful experiences for new Army nurses that occur during OBLC, the venue where nearly all new Army nurses begin their Army nursing careers. The course, OBLC, is approximately eight weeks in length and includes didactic Army leadership classroom instruction, Army clinical nursing-focused training, as well as a 3-week field training exercise (FTX) which consists of realistic combat nursing and medical operations training in an austere, field setting. This course is typically a new Army nurse's first experience in the U.S. Army Nurse Corps. For a fuller description of OBLC, refer to Appendix A. Of particular interest in this study will be the comparison of study variables during the beginning and ending weeks of OBLC as well as during the FTX which includes potentially stressful training events: the convoy training day and the mass casualty/triage training day. These field training exercise days were identified as particularly stressful field training days by the Deputy Director of the Development Leadership Branch at the Army Medical Center and School, the primary administrator of OBLC and all of its curricular training events (Personal communication, November 2, 2007.) These training days tend to be particularly stressful because they closely simulate actual combat activities and nursing care responsibilities.

Subjects and Sample Size: A convenience sample of up to 100 active duty Regular Army Nurse Corps officers will be obtained. Inclusion criteria are men and women, 21-46 years of age, attending eight-week increments of OBLC at the Army Medical Department's Center and School, Fort Sam Houston, in San Antonio, Texas between October 2008 and March 2009, who read and speak English. In order to qualify as an active duty Regular Army Nurse Corps Officer, one must meet the following conditions: 1) the prescribed medical and moral standards for appointment as a commissioned officer, 2) United States citizenship, 3) the Bachelor degree in nursing (BSN) or Master's degree in Nursing (MSN) from a nursing school accredited in the United States, 4) possess a valid, unrestricted RN license, and 5) be 21-46 years of age (exceptions may be granted to prior military service applicants) who meet the U.S. Army's physical and mental requirements for entry into the U.S. Army (U.S. Army Nurse Corps, 2008.) It is expected that the OBLC classes will closely reflect the gender and overall race and ethnic diversity of the U.S. Army Nurse Corps (U.S. Army Nurse Corps, 2006) as shown in Table 2:

Table 2: Gender and racial/ethnic diversity of active duty Regular Army Nurse Corps officers; U.S. Army Nurse Corps, 2006.

Female	Male	African American	Hispanic	Caucasian	Asian / Pacific Islander	American Indian	Other	TOTAL number
65%	35%	19%	5%	65%	7%	0.6%	3.3%	3117

There are no exclusion criteria for participation in this study. Access to the subject population for recruitment of study participants will be carefully coordinated with the Army Medical Department Center and School. A letter of agreement to participate in this study from an authorized representative of the Army Medical Department Center and School, COL Kathleen Duncan, Chief, Department of Nursing Science, or her designee, is on file with this study's investigators. The Army Medical Department Center and School (AMEDDC&S) site, a non-VCU institution, serves as a data collection site only. AMEDDC&S employees or agent will not be engaged in this research study. They will serve strictly as consultants to the investigators and will not interact with the Army nurses (or have access to any data records) on behalf of this research study.

The target convenience sample of up to 100 new Army nurses is based on access to two increments of OBLC which could potentially include from 100-500 Army nurses enrolled in OBLC. Each year, there are approximately five 8-week increments of OBLC offered. Each increment of OBLC can include between 50-250 Army nurses. The recommendation for a descriptive study with an alpha of 0.05, and an effect size of 0.9 is a sample size of 35 (Lipsey, 1990.) For this study, nearly three times that number will be enrolled to provide a more powerful description of the overall model and to allow analysis among demographic subgroups.

Variables and Measures: (See Table 1 for a summary of model cofactors.)

Biological factor. The hypothalamic-pituitary-adrenal (HPA) function is of particular interest in this study because of the relationship between perceived stress and elevated cortisol. Cortisol, is an indicator of hypothalamic-pituitary-adrenal (HPA) axis function and has well-established circadian rhythms (Kronfol, Nair, Zhang, et. al., 1997; Pfohl, Sherman, Schlechte, et. al., 1985.) Although salivary cortisol levels are significantly less concentrated than plasma cortisol levels, salivary cortisol is a reliable measure of stress reflecting the same circadian pattern as plasma cortisol. Salivary cortisol is preferable to serum cortisol because of the ease of repeated measurements over a 24-hour period and it is a less invasive means by which to collect samples from study participants in naturalistic settings (Gozansky, Lynn, & Laudenslager, et. al., 2005). Cortisol has been used as a measure of the HPA response in military and nursing stress related studies (Kobayashi, Furui, Akamatsu, et. al. 1997; Morgan, Wang Mason, et. al., 2000; Yang, Koh, Ng, et. al., 2001; Davydov, Shapiro, Goldstein, et. al., 2005; Nindl, Barnes, Alemany, et. al., 2007; Taylor, Sausen, Potterat, et. al., 2007). For this study, then, salivary cortisol will be used as the measurement of the biological factor, HPA function. A total of four salivary samples will be collected over 24-hours (30-minutes after arising, mid-day, afternoon, and evening) over four time points during OBLC: the beginning of OBLC, the convoy training exercise day, the mass casualty/triage training exercise day and the ending of OBLC. Cortisol levels at the beginning and ending of OBLC will be compared. Cortisol levels during the Field Training Exercise training days will be compared with levels from the beginning and ending of OBLC. Additionally, differences in cortisol levels will be compared statistically with demographic factors and psychological factors. One salivary cortisol sample collection should take approximately 1-2 minutes to collect (for a total of 4-8 minutes per day.) (See Appendix B, Salivary cortisol collection procedure.)

Demographic factors. A demographic questionnaire (See Appendix C) will be administered at the beginning of OBLC

to all study participants to include gender, age, race/ethnicity, marital status, number of children, years in professional nursing, prior military experience, and prior deployment experience. As potential cofactors, demographic factors such as prior nursing and/or military experience may be related to differences in stress in new Army nurses. This questionnaire should take approximately 5 minutes to complete.

Environmental factors. Environmental factors of stress provide information about stressful life events that represent significant changes in one's life. Environmental factors may reveal differences between Army nurses' impact of life experiences scores which may be related to, for example, military deployment experience. In this study, environmental factors will be measured using the Life Experiences Survey (LES, See Appendix D) developed by Sarason, Johnson, & Siegel (1978). It is a self-report questionnaire that gives the study participant the opportunity to rate the desirability or undesirability of different types of life experiences allowing for the relative contributions made by both negative and positive life changes that typically occur in the general population. It is comprised of a 57-items on a 7-point scale (-3 to +3) that reflects an impact range of the event in the individual's life (extremely negative impact to extremely positive). In addition, there are three open-ended, fill-in spaces to add events not included among the 57 items on the survey. Although checklist measures are known to be less predictive of outcomes than much lengthier, time-intensive interview measures (Cohen, Kessler, & Gordon, 1997), they are easier to administer since they do not require administration by trained interviewers. It is a moderately reliable instrument especially for test-retest of negative change scores (0.56-0.88, N = 345 university undergraduate students). Test-retest for positive change scores and total changes scores were not as reliable (0.19-0.53 and 0.63-0.64 respectively; Sarason, 2000.) The validity of the LES has been evaluated by comparing relationships between LES scores and the Spielberger State-Trait Anxiety Inventory (r = 0.29 for trait, r = 0.46 for state) among 100 undergraduate students. Additionally, LES negative change scores were more strongly related to depression scores on the Beck Depression Inventory (r = 0.37) than with the Recent Life Changes Questionnaire (r = 0.25). No known military or nursing studies use the LES to evaluate the stress response. In this study, the LES will be administered at the beginning of OBLC in order to determine new Army nurses' negative and positive impact of life experiences and to compare these outcomes with biological, demographic and psychological factors of stress during OBLC. This scale should take approximately 10 minutes to complete.

Psychological factors. Psychological factors of stress, such as perceived stress or perceived intrusiveness of a memory, provide descriptive information about the stress process. How perceived stress and intrusive, avoidant and hyperarousal symptoms are related to biological factors can increase our understanding of how the stress process can impact health outcomes. For example, Clow, Edwards & Owen, et. al. (2006) found that military recruits may not have been willing to reveal honest self-assessments in a competitive training situation. They studied salivary cortisol concentrations as well as self-rated psychological assessments of stress, arousal and fatigue in healthy army recruits. Although they found cortisol levels were sensitive to stressful time points during the training course, the self-rated assessments of perceived stress remained the same throughout the training course. Differences in psychological factors may be related to particular demographic factors of new Army nurses. How perceived stress can be related to biological factors will increase our understanding of the stress process. Psychological factors will be measured in this study using the Perceived Stress Scale (PSS) and the Impact of Event Scale-Revised (IES-R).

Perceived Stress Scale. Perceived stress will be measured using the Perceived Stress Scale (Cohen, Kamarck, & Mermelstein, 1983; see Appendix E). While Clow, Edwards & Owen, et. al. (2006) used the Cox-Mackay Stress Arousal Checklist (SACL) to measure perceived stress, there are no known studies that use the Cohen Perceived Stress Scale in military nurses. Yang, Koh, Ng, et. al. (2001) used a modified professional stress scale to compare stress between emergency department (ED, n = 23) and general ward (GW, n = 50) nurses in a general hospital. ED nurses perceived their job as more stressful when compared with GW nurses when they examined self-perceived work stress along with salivary cortisol levels. The PSS used in this dissertation study is a self-report questionnaire that assesses the domains of unpredictability, lack of control, burden overload, and stressful life circumstances. It is comprised of 14 items on a 5-point scale (0 = Never to 4 = Very often) and measures the degree to which events in the individual's life over the previous month were perceived as stressful. It is a valid and reliable instrument across diverse populations (Cohen, 2000) including two college student samples (Cronbach's alpha of 0.84, N = 332 and 114) and among working adults volunteering for a smoking cessation intervention (Cronbach's alpha of 0.86, N = 64). Each item in the PSS begins with the phrase, *In the last month, how often have you ...?* In this study, the PSS will be administered at the beginning and ending of OBLC in order to determine differences in perceived stress over the course of OBLC and to compare these measurement outcomes with salivary cortisol results as well as demographic and environmental factors during OBLC. The PSS should take approximately 3 minutes to complete.

Impact of Event Scale – Revised. Recent subjective distress for a specific potentially stressful event will be measured using the Impact of Event Scale – Revised (IES-R; Weiss & Marmar, 1997; see Appendix F). The 15-item

Impact of Event Scale (IES) was originally developed by Horowitz, Wilner, & Alvarez (1979) to capture the frequency of intrusive and avoidant symptoms over the previous seven days resulting from specific traumatic life events. The IES-R, however, includes an additional 7 items that assess hyperarousal symptoms. In this study, the beginning and ending of OBLC as well as the convoy training day and the mass casualty triage training day are each identified as potentially stressful events that participants will be asked to consider when completing the IES-R. The IES-R is self-report questionnaire that assesses the psychological response to traumatic stressors or stressful life events using intrusion, avoidance, and hyperarousal subscales. It is comprised of 22 items on a 5-point scale (ranging from "Not at all" to "Extremely") and measures how frequently each of the 22 difficulties identified in the scale has been distressing for the individual in the past 7 days with respect to the specific potentially stressful event. Items include, for example, *I tried not to think about it* and *I felt irritable and angry*. The original IES is a valid and reliable instrument with good to high internal consistency for subscale scores (Horowitz, Wilner, & Alvarez in Rush, First & Blacker, 2000). Cronbach's alpha ranged from 0.79 to 0.92 for the intrusion subscale and from 0.73 to 0.91 for the avoidance subscale. Correlations between the two subscales ranged from 0.57 to 0.78 at three different time points over the course of a year for persons receiving psychiatric therapy. For the IES-R, internal consistency of the three subscales is very high (Intrusion alpha = .87-.91, Avoidance alpha = .84-.86, and Hyperarousal alpha = .79-.90) using samples of hundreds of Interstate-880 freeway collapse victims and hundreds of Northridge earthquake victims in separate studies. The *IES-R* test-retest reliability data for the stability of variables over time for these same samples of victims did not yield as impressive results, however. Correlation coefficients were considerably higher in the Northridge earthquake victim sample than in the Interstate-880 freeway collapse victim sample (Intrusion = .57-.94, Avoidance = .51-.89, Hyperarousal = .59-.92.) These differences were likely due to a shorter interval between assessments and the greater recency of the traumatic event for the Northridge sample. In this study, the IES-R will be administered at four time points and each IES-R will specify a different stressful event for the study participant to consider: the beginning of OBLC, the convoy training exercise day, the mass casualty/triage training exercise day and the ending of OBLC. All IES-R scores will be compared to each other, to salivary cortisol results as well as to other study variables. This scale should take approximately 5 minutes to complete.

Study Procedures: The investigators in this study have successfully completed the CITI Course in The Protection of Human Research Subjects.

Recruitment. Following IRB approval, recruitment will proceed as follows. Participants will be recruited at the beginning of the eight-week AMEDD OBLC course increments offered between October 2008 and March 2009 at Fort Sam Houston, San Antonio, Texas. A convenience sample of up to 100 new Army nurses will be enrolled in the study. Approximately five OBLC increments are conducted per year with approximately 50-250 Army nurse attendees per increment. Recruitment efforts to increase the likelihood of accessing the desired sample in an efficient manner will be conducted and will include the following: 1) recruitment flyers (see Appendix G) will be posted on OBLC informational bulletin boards during the first week of each OBLC increment and 2) the student investigator, dressed in civilian clothing, will present a brief informational description of the study to the OBLC Army nurses as a group during the beginning of the first week of each course increment. The student investigator will wear civilian clothing during the brief informational description of the study since she is also an active duty Army nurse. Wearing civilian clothing instead of the military uniform should help minimize any undue influence over potential participants so that potential participants will not feel pressured to participate in the study.

Study Information Session. The study description presented to Army nurses approximately two to three times during the first week of OBLC and will include the purpose of the study, the informed consent process, the risks and benefits of participating in the study. It will also include information describing that the data will be used in the student investigator's individual study in an aggregated way such that no one's confidentiality is compromised. OBLC supervisory personnel will not be present during these this informational sessions; their presence could suggest undue influence over potential participants such that they may feel pressured to participate in the study. All potential study participants will be given written and verbal information describing the study and the informed consent form and the data collection schedule. Potential participants will be shown via demonstration by the student investigator how to collect their own salivary cortisol sample and that when they collect their salivary cortisol samples, they may do this in a private place of their choosing, for example, in the restroom. The potential participants will be instructed that their participation in this study is voluntary and that their military supervisors at OBLC will not be aware of whether or not they participate so that they will not feel pressured to participate. In addition, the participant may cease participation in the study at any time. The student investigator will include Brooke Army Medical Center inpatient, outpatient and emergency phone numbers and locations to study participants in the event they determine they need these services at any time during participation in this study. The study participant will be advised about privacy and confidentiality issues by the student investigator. The student investigator will explain that unidentifiable coding procedures will consist of each data record being assigned a

code number, and that identifying information will be removed from the data record and attached to the consent form, which will be kept separately from research data materials in a locked file accessible only by the student investigator and that all laboratory data will be coded such that identifying information will be removed from the lab sample. Additionally, study results will be aggregated. A code sheet with the participant's name and code number will be kept in a separate locked file and will be accessible to the study investigators.

All potential participants will receive a complimentary pen included in the packet of written materials whether they choose to participate in the study or not. The student investigator will provide her contact information (phone number and email address) on the recruitment flyer, during the informational sessions and in the packet of written information for any potential participant to contact the student investigator with questions about the study or about participation. Although all new Army nurses are expected to possess a college-level reading level, the consent and study materials are written at the 10th grade level. Nurses will decide whether or not they wish to participate in the research study after the informational session is complete. The study participant will read and sign the informed consent form if s/he wishes to participate and will place the signed consent form in the provided plain, unlabeled envelope at a collection point following the brief information session as instructed by the student investigator. The plain, unlabeled envelopes containing the informed consent forms will be collected and stored separately from any of the other research study materials in a locked file cabinet. *At the same time that the participant drops off the informed consent, s/he will pick up a research materials* packet to be completed as instructed throughout the remainder of OBLC (see Table 3).

Data collection procedure. Data collection will occur over four time points during Weeks 1, 5, 6, and 8 of each OBLC increment. Table 3 (below) summarizes the time points and criteria for collection. The research study material packet will contain salivary cortisol sample materials, the demographic questionnaire, the Life Experiences Survey, the Perceived Stress Scales, and the Impact of Event Scales-Revised in four packets labeled for collections during Week 1, Week 5, Week 6, and Week 8. Each week's completed research materials will be collected at a designated collection point identified by the student investigator at the time of the informational session. Data collected from study participants will include a total of 16 individual samples of salivary cortisol, one demographic questionnaire, one Life Experiences Survey (LES), two Perceived Stress Scales (PSS) and four Impact of Event Scales-Revised (IES-R.)

Week 1. Week 1 research packet materials will include the first day's salivary cortisol collection materials (4 samples total), the demographic questionnaire, the LES, one PSS and one IES-R to be completed any day during the first week of OBLC but no later than seven days after the brief description of the study that was provided by the student investigator. The identified stressful event for the IES-R is "beginning of OBLC" and will be completed on the same day as the salivary cortisol samples are collected, and on the same day as the demographic survey, the LES, and the first PSS are completed. Participants will be instructed to deposit completed Week 1 packets at a designated collection point as was instructed during the informational session during the first week of OBLC. The packet will consist of a plain, unlabeled envelope. Subjects will document the date of form completion on each data form. The student investigator will store the subject-coded research materials separately from the consent forms in a locked file cabinet.

Week 5. Week 5 packet materials will include one day's worth of salivary cortisol collection materials (4 samples total) and one IES-R. The identified stressful event for this IES-R is "convoy training exercise day." Salivary cortisol samples will be collected on "convoy training day" and the IES-R will be completed no later than seven days after "convoy training day". While the IES-R is event-specific, it may be completed up to seven days after the event. Participants will be instructed to deposit Week 5 packets at a designated collection point as was instructed during the informational session during the first week of OBLC. The packet will consist of a plain, unlabeled envelope. Subjects will document the date of form completion on each data form. The student investigator will store the subject-coded research materials separately from the consent forms in a locked file cabinet.

Week 6. Week 6 packet materials will include one day's worth of salivary cortisol collection materials (4 samples total) and one IES-R. The identified stressful event for this IES-R is "mass casualty triage training exercise day." (While the IES-R is event-specific, it may be completed up to seven days after the event. Salivary cortisol samples will be collected on "mass casualty triage training exercise day". Participants will be instructed to deposit Week 5 packets at a designated collection point as was instructed during the informational session during the first week of OBLC. The packet will consist of a plain, unlabeled envelope. Subjects will document the date of form completion on each data form. The student investigator will store the subject-coded research materials separately from the consent forms in a locked file cabinet.

Week 8. Week 8 packet materials will include one day's worth of salivary cortisol collection materials (4 samples total), one PSS and one IES-R to be completed any day during the last week of OBLC. The identified stressful event for the IES-R is "ending of OBLC" and will be completed at the time of the final PSS and the final day of salivary cortisol samples. Participants will be instructed to deposit Week 8 packets at a designated collection point as was instructed during

the informational session during the first week of OBLC. The packet will consist of a plain, unlabeled envelope. Subjects will document the date of form completion on each data form. The student investigator will store the subject-coded research materials separately from the consent forms in a locked file cabinet.

Table 3: Data collection schedule during an 8-week OBLC increment.

WEEK / VARIABLE	Week 1 Beginning of OBLC	Week 5 FTX Convoy training exercise day	Week 6 FTX Mass casualty triage training exercise day	Week 8 Ending of OBLC
Demographic Questionnaire[1]	X			
Life Experiences Survey (LES)[2]	X			
Perceived Stress Scale (PSS)[3]	X			X
Impact of Event Scale-Revised (IES-R)[4a-d]	X[4a]	X[4b]	X[4c]	X[4d]
Salivary Cortisol[5]	X	X	X	X

[1] Demographic questionnaire – To be completed during Week 1 of OBLC.
[2] LES – To be completed during Week 1 of OBLC.
[3] PSS – To be completed during Week 1 and Week 8 of OBLC.
[4a] IES-R – Identified stressful event is "beginning of OBLC"; to be completed at the time of the demographic survey, the LES, the first PSS and first day of salivary cortisol samples.
[4b] IES-R – Identified stressful event is "convoy training day"; to be completed no later than seven days after convoy training day.
[4c] IES-R – Identified stressful event is "mass casualty triage training day"; to be completed no later than seven days after mass casualty triage training day.
[4d] IES-R – Identified stressful event is "ending of OBLC"; to be completed at the time of the final PSS and final day of salivary cortisol samples.
[5] Salivary cortisol – Four samples collected per day (30-minutes after rising, mid-day, afternoon, and evening) on four separate days: any day during Week 1 ("beginning of OBLC"), on "convoy training day", on "mass casualty triage training day", and any day during Week 8 ("ending of OBLC").

Potential risks. This study presents no more than minimal risk to study participants. Subjects may experience some distress in recalling stressful events when completing the LES, PSS and IES-R instruments. Participants may be inconvenienced by providing saliva samples and completing demographic and psychosocial questionnaires. The time required to complete Week 1 study materials is approximately 25-30 minutes, Week 5 and Week 6 study materials each is approximately 9-13 minutes, and Week 8 study materials is approximately 12-16 minutes for a total of approximately one hour over the course of OBLC.

Risk reduction. This study presents no more than minimal risk to study participants. All study participants will be active duty military personnel and will have access to the inpatient and outpatient medical and psychological health care resources, if needed, through the military medical center system at Brooke Army Medical Center (BAMC) at Fort Sam Houston, San Antonio, Texas. To reduce risk to study participants, the student investigator will include BAMC inpatient, outpatient and emergency phone numbers and locations to study participants in the informed consent form in addition to

the brief informational description of the study provided during the beginning of the first week of each course increment.

Confidentiality. All data will be maintained by the study investigators. Study participants' identities will be kept confidential. Unidentifiable coding procedures will be used via a subject code number, with all identifying information removed. Data will be stored in a locked file cabinet. The consent form will be kept in a separate locked file cabinet accessible only by the study investigators. All survey and laboratory data will be coded. A code sheet with the participant's name and code number will be kept in a separate locked file and will be accessible to the study investigators. In addition, study results will be aggregated in order to maintain study participant confidentiality.

Privacy. The study participant will be advised about privacy issues by the student investigator at the time of the informational description of the study during the beginning of the first week of each course increment. The student investigator will provide contact information (phone number and email address) on the flyer and packet of written information for potential participants who have any questions about the study and/or their potential research participation. Potential participants will be instructed that they may collect their salivary cortisol samples in a private place of their choosing, for example, in the restroom 30 minutes after rising and before eating lunch. Survey instruments may be completed at the participant's convenience in a private place of their choosing per Table 3 data collection requirements. Packets of completed consent forms and study materials to be deposited at designated collection points will be plain, unlabeled envelopes.

Risk/Benefit. The minimal risk to study participants is reasonable given the benefit of understanding the baseline factors of stress in new Army nurses and how these factors may be related to stress experiences throughout an Army nurse's career.

Compensation Plan. All potential participants will receive a complimentary pen included in the study packet at the time of the informational session whether they choose to participate or not.

Consent. Following IRB approval and prior to any data collection, the informed consent will be obtained from those who wish to participate in this research study. New Army nurses enrolled in one or more eight-week Officer Basic Leadership Course increments between October 2008 and March 2009 will be offered the opportunity to consent to participate in this study. The student investigator will be obtaining the consent in the English language at the 10th grade level reading ability. The student investigator will present a brief informational description of the study including the purpose of the study, the informed consent process, the risks and benefits of participating in the study and that the information obtained will be used in the student investigator's individual study in an aggregated way such that no one's confidentiality is compromised. All potential study participants will be given written and verbal information describing the study. The study participant will be advised about privacy and confidentiality issues by the student investigator. The potential participants will be instructed that their participation in this study is strictly voluntary and that their military supervision at ORLC will not be aware of whether or not they participate. Potential participants will be informed that they may end their participation in the study at any time if they feel it is in their best interest to do so. The student investigator will provide her contact information (phone number and email address) on the recruitment flyer, during the informational sessions and in the packet of written information for potential participants in the event any of the potential study participants have questions about the study and/or their potential study participation. Potential study participants will decide whether or not to participate in the study following the information session given by the student investigator (approximately one hour.) Consent to participate in this study will be documented by the completion and return of the signed consent form. Potential study participants will be instructed where the designated collection point will be for study participants to deposit their signed informed consent forms. Completed consents will be enclosed in plain, unlabeled envelopes at the designated collection point. The designated collection point for signed consent forms will be identified by the student investigator at the time of the brief informational description of the study. The student investigator will then separate the consent from any other identifying information and the consent forms will be stored separately in a locked cabinet separate from any other research study materials.

X. PLAN FOR CONTROL OF INVESTIGATIONAL DRUGS (If the VCUHS Investigational Drug Pharmacy is not used), DEVICES, AND BIOLOGICS

Describe your plans for the control of investigational products including: (1) how you will maintain records of the product's delivery to the trial site, the inventory at the site, the use by each subject, and the return to the sponsor or alternative disposition of unused product(s); (2) plan for storing the investigational product(s) as specified by the sponsor (if any) and in accordance with applicable regulatory requirements; (3) plan for ensuring that the investigational product(s) are used only in accordance with the approved protocol; and (4) how you will ensure that each subject understands the correct use of the investigational product(s) (if applicable) and check that each subject is following the instructions properly (on an ongoing basis).

NA.

XI. DATA ANALYSIS PLAN
For investigator-initiated studies.

The specific aim of this project is to examine, within a sample of new Army nurses, the relationship among selected biological, demographic, environmental and psychological factors related to stress during attendance at the eight-week Officer Basic Leadership Course. Descriptive statistics will be used to summarize the sample. Where appropriate, means and standard deviations or frequencies and percents will be calculated for all of the biological, demographic, environmental and psychological factors. Assessment of possible relationships between these variables will be conducted by calculating Pearson's correlation coefficients (between continuous variables), ANOVA (between pairs of continuous and categorical variables) and contingency table analysis (between categorical variables). Stepwise regression models will be built to understand the relationship between the change in stress (from the beginning to the ending of OBLC) and the demographic, biological and environmental variables. A repeated measures model will be fit to formally test for changes in the Perceived Stress Scale, the Impact of Event Scale and salivary cortisol.

XII. DATA AND SAFETY MONITORING

- If the research involves greater than minimal risk and there is no provision made for data and safety monitoring by any sponsor, include a data and safety-monitoring plan that is suitable for the level of risk to be faced by subjects and the nature of the research involved.
- If the research involves greater than minimal risk, and there is a provision made for data and safety monitoring by any sponsor, describe the sponsor's plan.
- If you are serving as a Sponsor-Investigator, identify the Contract Research Organization (CRO) that you will be using and describe the provisions made for data and safety monitoring by the CRO. Guidance on additional requirements for Sponsor-Investigators is available at http://www.research.vcu.edu/irb/wrap/flash/wrap_guide.htm#X-2.htm

The specific aim of this project is to examine, within a sample of new Army nurses, the relationships among selected biological, demographic, environmental and psychological factors related to stress during their attendance at the eight-week Officer Basic Leadership Course. The dissertation committee will serve as a quality review panel. The principal and student investigators will be responsible for data and safety monitoring and will periodically review (approximately every other week) all aspects of the study including IRB compliance. Additionally, a thorough review of the study will be conducted after Week 1 research study materials are completed and collected. This review will include an analysis of any adverse events. This study is a minimal risk study and no adverse events are expected. However, if an adverse event occurs, the student investigator will assume responsibility for (a) notification of and, if indicated, referral of the study participant to Brooke Army Medical Center, Fort Sam Houston, San Antonio, Texas as needed; (b) notification of the study's principal investigator, Dr. Mary Jo Gnap, and the Associate Dean of the School of Nursing at VCU, Dr. Janet Younger; and (c) notification of the VCU and Brooke Army Medical Center IRBs. In accordance with Federal and institutional policies, coded participant data will be available to authorized persons and entities. These data will be electronically archived under the supervision of the dissertation committee member, Dr. R.K. Elswick. Confidentiality of participant data is the primary safety-related issue in this study. Participants' identities will be protected. Each data record will be assigned a subject code number, identifying information will be removed from the data record and attached to the consent form, which will be kept in a locked file accessible only by the student investigator. A code sheet with the participant's name and code number will be kept in a separate locked file and will be accessible to the study investigators. All survey and laboratory data will be coded and stored in a locked cabinet separate from the consent forms and code sheet.

XIII. MULTI-CENTER STUDIES
If VCU is the lead site in a multi-center project or the VCU PI is the lead investigator in a multi-center project, describe the plan for management of information that may be relevant to the protection of subjects, such as reporting of unexpected problems, project modifications, and interim results.

NA

XIV. INVOLVEMENT OF NON-VCU INSTITUTIONS/SITES (DOMESTIC AND FOREIGN)

1. **Provide the following information for each non-VCU institution/site (domestic and foreign) that has agreed to participate:**
   - **Name of institution/site**
   - **Contact information for institution/site**

A letter of agreement to participate in this study from an authorized representative of the Army Medical Department Center and School, COL Kathleen Dunemn, Chief, Department of Nursing Science, or her designee, is on file with this study's investigators.
Army Medical Department Center & School (AMEDDC&S)
Fort Sam Houston, San Antonio, Texas
Contact information for institution/site:
Kathleen Dunemn, PhD, RN, CNM
Colonel, US Army Nurse Corps
Chief, Department of Nursing Science
ATTN MCCS-HN
3490 Forage Road, Bldg 1394
Fort Sam Houston, TX 78234-7585
(210) 295-4787
Email: kathleen.dunemn2@amedd.army.mil

2. **For each institution, indicate whether or not it is "engaged" in the research (see OHRP's guidance on "Engagement of Institutions in Research" at http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm.)**

For this research study, the Army Medical Department Center & School (AMEDDC&S) is not "engaged" in research per OHRP guidance on "Engagement of Institutions in Research."

3. **Provide a description of each institution's role (whether engaged or not) in the human subjects research, adequacy of the facility (in order to ensure human subject safety in the case of an unanticipated emergency), responsibilities of its agents/employees, and oversight that you will be providing in order to ensure adequate and ongoing protection of the human subjects. You should only identify institutions that have agreed to participate. If additional institutions agree to participate at a later time, they must be added by amendment to the protocol.**

The AMEDDC&S is not "engaged" in research per OHRP guidance on "Engagement of Institutions in Research." The AMEDDC&S site serves strictly as a data collection site only. AMEDDC&S employees or agents will not be "engaged" in this research study. They will serve strictly as consultants to the study investigators and will not interact with the Army nurses (or have access to any data records) on behalf of this research study. This study presents no more than minimal risk to study participants. All study participants will be active duty military personnel and will have access to the local inpatient and outpatient medical and psychological health care resources, if needed, through the local military medical center system at Brooke Army Medical Center (BAMC) at Fort Sam Houston, San Antonio, Texas. To reduce risk to study participants, the student investigator will include BAMC inpatient, outpatient and emergency phone numbers and locations to study participants in the informed consent form in addition to the brief informational description of the study provided during the beginning of the first week of each course increment.

4. **For each institution that is "engaged" provide an OHRP Federalwide Assurance (FWA) # if: (1) the research is not exempt, AND (2) the research involves a DIRECT FEDERAL award made to VCU (or application for such).**

NOTE: Additional guidance at http://www.research.vcu.edu/irb/wrpp/flash/wrpp_guide.htm#XVII-6.htm, and http://www.research.vcu.edu/irb/wrpp/flash/wrpp_guide.htm#XVII-11.htm.

NA. (The AMEDDC&S is not "engaged" in this research study.)

XV. INVOLVEMENT OF INDEPENDENT INVESTIGATORS

INDEPENDENT INVESTIGATOR: an individual who is acting independently and not acting as an agent or employee of any institution or facility while carrying out his or her duties in the research protocol. Additional guidance at http://www.research.vcu.edu/irb/wpp/flash/wpp_guide.htm#XVII-15.htm.

ENGAGEMENT IN RESEARCH: An independent investigator becomes "engaged" in human subjects research when he/she (i) intervenes or interacts with living individuals for research purposes; or (ii) obtains individually identifiable private information for research purposes [45 CFR 46.102(d)-(f)]. See OHRP's guidance on "Engagement of Institutions in Research" at http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm.

1. Provide a list of independent investigators.

2. For each independent investigator indicate whether or not he/she is "engaged" or "not engaged" in the research

3. For each independent investigator who is "engaged": (1) describe his/her role with human subjects/identifiable human data, AND (2) describe YOUR oversight of his/her involvement.

NA. (THERE ARE NO "INDEPENDENT INVESTIGATORS" IN THIS RESEARCH STUDY.)

NOTE: If an independent investigator is "engaged," and the research is (1) not exempt AND (2) involves a DIRECT FEDERAL award made to VCU (or application for such), the independent investigator must sign a formal written agreement with VCU certifying terms for the protection of human subjects. For an agreement to be approved: (1) the PI must directly supervise all of the research activities, (2) agreement must follow the ORSP template, (3) IRB must agree to the involvement of the independent investigator, AND (4) agreement must be in effect prior to final IRB approval.

XVI. HUMAN SUBJECTS INSTRUCTIONS (Be sure to use the sub-headings under A-I)
ALL sections of the Human Subjects Instructions must be completed with the exception of the section entitled "Special Consent Provisions." Complete that section if applicable.

A. DESCRIPTION
Provide a detailed description of the proposed involvement of human subjects or their private identifiable data in the work.

The purpose of this dissertation research is to describe relationships among biological, demographic, environmental and psychological factors of stress in new Army nurses as they begin their Army nursing careers. This study will focus on potentially stressful experiences for new Army nurses during the Officer Basic Leadership Course (OBLC), the venue where nearly all new Army nurses begin their Army nursing careers. The specific aim of this project is to examine, within a sample of new Army nurses, the relationships among selected biological, demographic, environmental and psychological factors related to stress during attendance at the eight-week OBLC. The study setting for this study will be the Army Medical Department's OBLC at Fort Sam Houston, San Antonio, Texas. Of particular interest in this study will be the comparison of biological, demographic, environmental and psychological factors during the beginning and ending weeks of OBLC as well as during the austere field training exercise which includes two potentially stressful training events, convoy training day and mass casualty triage training day. A convenience sample of up to 100 active duty Regular Army Nurse Corps officers will be obtained, including men and women, 21-46 years of age, attending the eight-week increments of OBLC at the Army Medical Department's Center and School, Fort Sam Houston, in San Antonio, Texas between October 2008 and March 2009 and who read and speak English will be recruited. Approximately five OBLC increments are conducted per year with approximately 50-250 Army nurse attendees per increment. Following informed consent and study enrollment, study participants will be asked to complete four packets of research study materials during OBLC, one study packet during each of Weeks 1, 5, 6, and 8 according to the data collection schedule (see Table 3) which will include salivary cortisol samples, a demographic questionnaire, the Life Experiences Survey, the Perceived Stress Scale, and the Impact of Event Scale-Revised.

B. SUBJECT POPULATION

Describe the subject population in terms of sex, race, ethnicity, age, etc., and your access to the population that will allow recruitment of the necessary number of participants. Identify the criteria for inclusion or exclusion of any subpopulation and include a justification for any exclusion. Explain the rationale for the involvement of special cases of subjects, such as children, pregnant women, human fetuses, neonates, prisoners or others who are likely to be vulnerable. If you plan to allow for the enrollment of Wards of the State (or any other agency, institution, or entity), you must specifically request their inclusion and follow guidance on Wards and Emancipated Minors in the VCU IRB Written Policies and Procedures (specifically WPP#: XV-3) available at http://www.research.vcu.edu/irb/wpp/flash/wpp_guide.htm#XV-3.htm.

Subject Population Description and Inclusion Criteria: The subject population includes all Army nurses, men and women, who meet the U.S. Army Nurse Corps requirements for active duty Regular Army appointment as an Officer in the U.S. Army Nurse Corps and are attending any increment of the eight-week Officer Basic Leadership Course (OBLC) at the Army Medical Department Center and School at Fort Sam Houston in San Antonio, Texas between October, 2008 and March, 2009. A convenience sample of up to 100 new Army nurses will be obtained. Approximately five OBLC increments are conducted per year with approximately 50-250 Army nurse attendees per increment. In order to qualify as an active duty Regular Army Nurse Corps Officer, one must meet the following conditions: 1) the prescribed medical and moral standards for appointment as a commissioned Officer, 2) United States citizenship, 3) the Bachelor degree in nursing (BSN) or Master's degree in Nursing (MSN) from a nursing school accredited in the United States, 4) possess a valid, unrestricted RN license, and 5) be 21-46 years of age (exceptions may be granted to prior military service applicants) who meet the U.S. Army's physical and mental requirements for entry into the U.S. Army (U.S. Army Nurse Corps, 2008.) It is expected that the OBLC classes will reflect gender and overall race and ethnic diversity of the U.S. Army Nurse Corps (U.S. Army Nurse Corps, 2006) as shown in Table 2. Access to this subject population will allow for recruitment of a convenience sample of up to 100 Active Duty Regular Army Nurse Corps officers, including men and women, 21-46 years of age, attending the eight-week increments of OBLC at the Army Medical Department's Center and School, Fort Sam Houston, in San Antonio, Texas between October 2008 and March 2009 and who read and speak English. There are no exclusion criteria for participation in this study.
Subject Population Access: Access to the subject population for recruitment of study participants will be carefully coordinated with the Army Medical Department Center and School (AMEDDC&S.) A letter of agreement for the AMEDDC&S to participate in this research study from an authorized representative of the Army Medical Department Center and School is on file with the study investigators.

C. Research Material

Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

Using the data collection schedule in Table 3, data collected from consented participants will occur over four time points during Weeks 1, 5, 6, and 8. Following consent to participate in this study, sources of research material will potentially include from each study participant a total of 16 individual samples of salivary cortisol, one completed demographic questionnaire, one completed Life Experiences Survey (LES), two completed Perceived Stress Scales (PSS) and four completed Impact of Event Scales-Revised (IES-R.) The data and material will be obtained specifically for research purposes. No existing specimens, records, or data will be collected.

D. Recruitment Plan

Describe in detail your plans for the recruitment of subjects including: (1) how potential subjects will be identified (e.g., school personnel, health care professionals, etc.), (2) how you will get the names and contact information for potential subjects, and (3) who will make initial contact with these individuals (if relevant) and how that contact will be done. If you plan to involve special cases of subjects, such as children, pregnant women, human fetuses, neonates, prisoners or others who are likely to be vulnerable, describe any special recruitment procedures for these populations.

Following IRB approval, recruitment will proceed as follows. Participants will be recruited at the beginning of the eight-week AMEDD OBLC course increments offered between October 2008 and March 2009 at Fort Sam Houston, San Antonio, Texas. Access to the subject population for recruitment of study participants will be carefully coordinated with

the Army Medical Department Center and School. A convenience sample of up to 100 new Army nurses will be enrolled in the study. Approximately five OBLC increments are conducted per year with approximately 50-250 Army nurse attendees per increment. Recruitment efforts to increase the likelihood of accessing the desired sample in an efficient manner will be conducted and will include the following: 1) recruitment flyers (see Appendix G) will be posted on OBLC informational bulletin boards during the first week of each OBLC increment and 2) the student investigator, dressed in civilian clothing, will present a brief informational description of the study to the OBLC Army nurses as a group during the beginning of the first week of each course increment. The student investigator will wear civilian clothing during the brief informational description of the study since she is also an active duty Army nurse. Wearing civilian clothing instead of the military uniform should help minimize any undue influence over potential participants so that potential participants will not feel pressured to participate in the study.

Study Information Session. The study description presented to Army nurses approximately two to three times during the first week of OBLC and will include the purpose of the study, the informed consent process, the risks and benefits of participating in the study. The study description will include the purpose of the study, the informed consent process, the risks and benefits of participating in the study. It will also include information describing that the data will be used in the student investigator's individual study in an aggregated way such that no one's confidentiality is compromised. OBLC supervisory personnel will not be present during this informational sessions; their presence could suggest undue influence over potential participants such that they may feel pressured to participate in the study. All potential study participants will be given written and verbal information describing the study, the informed consent form, and the data collection schedule. Potential participants will be shown via demonstration by the student investigator how to collect their own salivary cortisol sample and that when they collect their salivary cortisol samples, they may do this in a private place of their choosing, for example, in the restroom. The potential participants will be instructed that their participation in this study is voluntary and that their military supervisors at OBLC will not be aware of whether or not they participate so that they will not feel pressured to participate. In addition, the participant may cease participation in the study at any time. The student investigator will include Brooke Army Medical Center inpatient, outpatient and emergency phone numbers and locations to study participants in the event they determine they need these services at any time during participation in this study. The study participant will be advised about privacy and confidentiality issues by the student investigator. The student investigator will explain that unidentifiable coding procedures will consist of each data record being assigned a code number, and that identifying information will be removed from the data record and attached to the consent form, which will be kept separately from research data materials in a locked file accessible only by the student investigator and that all laboratory data will be blindly and coded and that study results will be aggregated. A code sheet with the participant's name and code number will be kept in a separate locked file and will be accessible to the study investigators.

All potential participants will receive a complimentary pen included in the packet of written materials whether they choose to participate in the study or not. The student investigator will provide her contact information (phone number and email address) on the flyer, during the informational sessions and in the packet of written information for any potential participant to contact the student investigator with questions about the study or about participation. Although all new Army nurses are expected to possess a college-level reading level, the consent and study materials are written at the 10th grade level. Nurses will decide whether or not they wish to participate in the research study after the informational session is complete. The study participant will read and sign the informed consent form if s/he wishes to participate and will place the signed consent form in the provided plain, unlabeled envelope at a collection point following the brief information session as instructed by the student investigator. The plain, unlabeled envelopes containing the informed consent forms will be collected and stored separately from any of the other research study materials in a locked file cabinet. At the same time that the participant drops off the informed consent, s/he will pick up a research materials packet to be completed as instructed throughout the remainder of OBLC (see Table 3).

E. POTENTIAL RISKS

Describe potential risks whether physical, psychological, social, legal, or other and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.

This study presents no more than minimal risk to study participants. Subjects may experience some distress in recalling stressful events when completing the LES, PSS and IES-R surveys. Participants may be inconvenienced by providing saliva samples and completing demographic and psychosocial questionnaires. The time required to complete, for example, Week 1 study materials is approximately 25-30 minutes, Week 5 and Week 6 study materials each is approximately 9-13 minutes, and Week 8 study materials is approximately 12-16 minutes for a total of approximately one hour over the course

of OBLC.

F. RISK REDUCTION

Describe the procedures for protecting against or minimizing potential risk. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse events to the subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of subjects.

This study presents no more than minimal risk to study participants. All study participants will be active duty military personnel and will have access to the inpatient and outpatient medical and psychological health care resources, if needed, through the military medical center system at Brooke Army Medical Center (BAMC) at Fort Sam Houston, San Antonio, Texas. To reduce risk to study participants, the student investigator will include BAMC inpatient, outpatient and emergency phone numbers and locations to study participants in the informed consent form in addition to the brief informational description of the study provided during the beginning of the first week of OBLC.

G. ADDITIONAL SAFEGUARDS IF ANY PARTICIPANTS WILL BE VULNERABLE

Describe any additional safeguards to protect the rights and welfare of participants if you plan to involve special cases of subjects, such as children, pregnant women, human fetuses, neonates, prisoners or others who are likely to be vulnerable. Safeguards to protect the rights and welfare of participants might relate to Inclusion/Exclusion Criteria: ("Adults with moderate to severe cognitive impairment will be excluded." "Children must have diabetes. No normal controls who are children will be used.") Consent: ("Participants must have an adult care giver who agrees to the participant taking part in the research and will make sure the participant complies with research procedures." "Adults must be able to assent. Any dissent by the participant will end the research procedures.") Benefit: ("Individuals who have not shown benefit to this type of drug in the past will be excluded.").

NA.

H. CONFIDENTIALITY

Describe how the confidentiality of data collected as part of this project will be protected including pre-screening data (e.g., physical controls on the data; access controls to the data; coding of data; legal controls, such as a Federal Certificate of Confidentiality; statistical methods; or reporting methods).

All data will be maintained by the investigator and identities will be protected. Unidentifiable coding procedures will consist of each data record being assigned a subject code number by the student investigator. Identifying information will be removed from the data record and attached to the consent form and kept in a locked cabinet accessible only by the study investigators. A code sheet with the participant's name and code number will be kept in a separate locked file and will be accessible to the study investigators. All survey and laboratory data will be coded. In addition, study results will be aggregated.

I. PRIVACY

Describe how the privacy interests of subjects will be protected where privacy refers to persons and their interests in controlling access to themselves, and assess their likely effectiveness. Identify what steps you will take for subjects to be comfortable: (1) in the research setting and (2) with the information being sought and the way it is sought.

The study participant will be advised about privacy issues by the student investigator at the time of the informational description of the study to the Army nurses during the beginning of the first week of each course increment. The student investigator will provide contact information (phone number and email address) on the recruitment flyer and packet of written information for potential participants who have any questions about the study and/or their potential research participation. Potential participants will be instructed that they may collect their salivary cortisol samples in a private place of their choosing, for example, in the restroom 30 minutes after rising and before eating lunch. Survey instruments may be completed at the participant's convenience in a private place of their choosing per Table 3 data collection requirements. Packets of completed consent forms and study materials to be deposited at designated collection points will be plain, unlabeled envelopes.

J. RISK/BENEFIT

Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result. If a test article (investigational new drug, device, or biologic) is involved, name the test article and supply the FDA approval letter.

The minimal risk to participants is reasonable given the benefit of learning about the baseline factors of stress in new Army nurses and how these factors may be related to stress experiences throughout an Army nurse's career.

K. COMPENSATION PLAN

Compensation for subjects (if applicable) should be described, including possible total compensation, any proposed bonus, and any proposed reductions or penalties for not completing the project.

All potential participants will receive a complimentary pen included in the study packet whether they choose to participate or not.

L. CONSENT ISSUES

1. CONSENT PROCESS

Indicate who will be asked to provide consent/assent, who will obtain consent/assent, what language (e.g., English, Spanish) will be used by those obtaining consent/assent, where and when will consent/assent be obtained, what steps will be taken to minimize the possibility of coercion or undue influence, and how much time will subjects be afforded to make a decision to participate.

Following IRB approval and prior to any data collection, the informed consent will be obtained from those who wish to participate in this research study. New Army nurses enrolled in one or more eight-week Officer Basic Leadership Course increments between October 2008 and March 2009 will be offered the opportunity to consent to participate in this study. The student investigator will be obtaining the consent in the English language at the 10th grade level reading ability. The student investigator will present a brief informational description of the study including the purpose of the study, the informed consent process, the risks and benefits of participating in the study and that the information obtained will be used in the student investigator's individual study in an aggregated way such that no one's confidentiality is compromised. The student investigator will wear civilian clothing during the brief informational description of the study since she is also an active duty Army nurse. Wearing civilian clothing instead of the military uniform should help minimize any undue influence over potential participants so that potential participants will not feel pressured to participate in the study. All potential study participants will be given written and verbal information describing the study. The potential participants will be instructed that their participation in this study is strictly voluntary and that their military supervision at OBLC will not be aware of whether or not they participate. The study participant will be advised about privacy and confidentiality issues by the student investigator. Potential participants will be informed that they may end their participation in the study at any time if they feel it is in their best interest to do so. The student investigator will provide her contact information (phone number and email address) on the flyer, during the informational sessions and in the packet of written information for potential participants in the event any of the potential study participants have questions about the study and/or their potential study participation. Potential study participants will decide whether or not to participate in the study following the information session provided by the student investigator (approximately one hour.) Consent to participate in this study will be documented by the completion and return of the signed consent form. Potential study participants will be instructed where the designated collection point will be for study participants to deposit their signed informed consent forms. Completed consents will be enclosed in plain, unlabeled envelopes at the designated collection point. The designated collection point for signed consent forms will be identified by the student investigator at the time of the brief informational description of the study. The student investigator will then separate the consent from any other identifying information and the consent forms will be stored separately in a locked cabinet separate from any other research study materials.

2. SPECIAL CONSENT PROVISIONS

If some or all subjects will be cognitively impaired, or have language/hearing difficulties, describe how capacity for consent will be determined. Please consider using the VCU Informed Consent Evaluation Instrument available at http://www.research.vcu.edu/irb/guidance.htm. If you anticipate the need to obtain informed consent from legally authorized representatives (LARs), please describe how you will identify an appropriate representative and ensure

that their consent is obtained. Guidance on LAR is available at http://www.research.vcu.edu/irb/wpp/flash/wpp_guide.htm#XI-3.htm.

NA.

3. If request is being made to WAIVE SOME OR ALL ELEMENTS OF INFORMED CONSENT FROM SUBJECTS OR PERMISSION FROM PARENTS, explain why: (1) the research involves no more than minimal risk to the subjects, (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects, (3) the research could not practicably be carried out without the waiver or alteration; AND (4) whether or not subjects will be debriefed after their participation. Guidance is available at http://www.research.vcu.edu/irb/wpp/flash/wpp_guide.htm#XI-1.htm.. NOTE: Waiver is not allowed for FDA-regulated research unless it meets FDA requirements for Waiver of Consent for Emergency Research (see below).

NA.

4. If request is being made to WAIVE DOCUMENTATION OF CONSENT, provide a justification for waiver based on one of the following two elements AND include a description of the information that will be provided to participants: (1) the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Subject will be asked whether they want documentation linking them with the research, and each subject's wishes will govern; or (2) the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. Guidance is available at http://www.research.vcu.edu/irb/wpp/flash/wpp_guide.htm#XI-2.htm

NA.

5. If applicable, explain the ASSENT PROCESS for children or decisionally impaired subjects. Describe the procedures, if any, for re-consenting children upon attainment of adulthood. Describe procedures, if any, for consenting subjects who are no longer decisionally impaired. Guidance is available at http://www.research.vcu.edu/irb/wpp/flash/wpp_guide.htm#XV-2.htm and http://www.research.vcu.edu/irb/wpp/flash/wpp_guide.htm#XVII-7.htm.

NA.

6. If request is being made to WAIVE THE REQUIREMENT TO OBTAIN ASSENT from children age 7 or higher, or decisionally impaired subjects, explain why: (1) why some or all of the individuals age 7 or higher will not be capable of providing assent based on their developmental status or impact of illness; (2) the research holds out a prospect of direct benefit not available outside of the research; AND/OR (3) [a] the research involves no more than minimal risk to the subjects, [b] the waiver or alteration will not adversely affect the rights and welfare of the subjects, [c] the research could not practicably be carried out without the waiver or alteration; AND [d] whether or not subjects will be debriefed after their participation. Guidance is available at http://www.research.vcu.edu/irb/wpp/flash/wpp_guide.htm#XV-2.htm

NA.

7. If request is being made to waive consent for emergency research, see guidance at http://www.research.vcu.edu/irb/wpp/flash/wpp_guide.htm#XVII-16.htm.

NA.

8. If applicable, address the following issues related to GENETIC TESTING:

a. FUTURE CONTACT CONCERNING FURTHER GENETIC TESTING RESEARCH
Describe the circumstances under which the subject might be contacted in the future concerning further participation in this or related genetic testing research.

NA.

b. FUTURE CONTACT CONCERNING GENETIC TESTING RESULTS
If planned or possible future genetic testing results are unlikely to have clinical implications, then a statement that the results will not be made available to subjects may be appropriate. If results might be of clinical significance, then describe the circumstances and procedures by which subjects would receive results. Describe how subjects might access genetic counseling for assistance in understanding the implications of genetic testing results, and whether this might involve costs to subjects. Investigators should be aware that federal regulations, in general, require that testing results used in clinical management must have been obtained in a CLIA-certified laboratory.

NA.

c. WITHDRAWAL OF GENETIC TESTING CONSENT
Describe whether and how subjects might, in the future, request to have test results and/or samples withdrawn in order to prevent further analysis, reporting, and/or testing.

NA.

d. GENETIC TESTING INVOLVING CHILDREN OR DECISIONALLY IMPAIRED SUBJECTS
Describe procedures, if any, for consenting children upon the attainment of adulthood. Describe procedures, if any, for consenting subjects who are no longer decisionally impaired.

NA.

e. CONFIDENTIALITY
Describe the extent to which genetic testing results will remain confidential and special precautions, if any, to protect confidentiality.

NA.

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Describing Stress in New Army Nurses
Otto, Laureen A.
App. B

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JUL 28 [illegible]

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For Research Use

Intended Use

The Salimetrics™ cortisol kit is a competitive immunoassay specifically designed and validated for the quantitative measurement of salivary cortisol. It is not intended for diagnostic use. It is intended only for research use in humans and some animals. Please read the complete kit insert before performing this assay. For further information about this kit, its application, or the procedures in this insert, please contact the technical service team at Salimetrics or your local sales representative.

Introduction

Historically, the immunodiagnostic community's approach to the application of immunoassay techniques in the measurement of biomarkers in saliva has been problematic. This assay kit was designed to address these problems. First, prior to the late 1990s the majority of available immunoassays for saliva cortisol were modifications of protocols developed for use with serum/plasma. The standards used in these assay kits were suspended in a human serum matrix. Given that the composition of serum is markedly different from saliva, these standards are likely to produce results that are influenced by matrix differences. To ensure the most accurate results, this salivary immunoassay uses a matrix that matches saliva. Second, the level of cortisol in saliva is significantly lower than levels in the general circulation. The use of a standard curve developed to capture the range of values expected in serum/plasma samples is often not sensitive enough to capture the complete range of individual differences in the level expected in saliva. This assay was designed to capture the full range of salivary cortisol levels (0.003 to 3.0 µg/dL) while using only 25 µL of saliva per test. Third, the pH of saliva is easily lowered or raised by the consumption of food or drink. Performance of immunoassays becomes compromised as the pH of samples to be tested drops below 4 (1). This results in artificially inflated levels. This assay system is designed to be resilient to the effects of interference caused by collection techniques that affect pH. In addition, a built-in pH indicator warns the user of acidic or basic samples.

Test Principle

A microtitre plate is coated with monoclonal antibodies to cortisol. Cortisol in standards and unknowns competes with cortisol linked to horseradish peroxidase for the antibody binding sites. After incubation, unbound components are washed away. Bound cortisol peroxidase is measured by the reaction of the peroxidase enzyme on the substrate tetramethylbenzidine (TMB). This reaction produces a blue color. A yellow color is formed after stopping the reaction with sulfuric acid. Optical density is read on a standard plate reader at 450 nm. The amount of cortisol peroxidase detected is inversely proportional to the amount of cortisol present (2).

pH Indicator

A pH indicator in the assay diluent alerts the user to samples with high or low pH values. Acidic samples will turn the diluent yellow. Alkaline samples will turn the diluent purple. Dark yellow or purple wells indicate that a pH value for that sample should be obtained using pH strips. Cortisol values from samples with a pH ≤ 3.5 or ≥ 9.0 may be artificially inflated or lowered (1).

Precautions

1. Liquid stop solution is a 3-molar solution of sulfuric acid. This solution is caustic; use with care. Stop solution in powdered form is not sulfuric acid-based and is mildly corrosive.
2. This kit uses break-apart microtitre strips. Unused wells must be stored at 2 - 8°C in the sealed foil pouch with desiccant and used in the frame provided.
3. Do not mix components from different lots of kits.
4. When using a multichannel pipette, reagents should be added to duplicate wells at the same time. Follow the same sequence when adding additional reagents so that incubation time with reagents is the same for all wells.
5. See "Material Safety Data" at the end of procedure.
6. As for all quantitative assays for salivary analytes, we recommend that samples be screened for possible blood contamination (3,4). This can be efficiently and economically accomplished using the Salimetrics Blood Contamination EIA Kit (Cat. No.: 1-1302/1-1312). Do not use dipsticks, which result in false positive values due to salivary enzymes.
7. Routine calibration of pipettes is critical for the best possible assay performance.
8. Pipetting of samples and reagents must be done as quickly as possible (without interruption) across the plate.
9. When running multiple plates, or multiple sets of strips, a standard curve should be run with each individual plate and/or set of strips.
10. The temperature of the laboratory may affect assays. Salimetrics' kits have been validated at 68 - 74°F (20 - 23.3°C). Higher or lower temperatures will cause an increase or decrease in OD values, respectively. Salimetrics cannot guarantee test results outside of this temperature range.
11. The quantity of reagent provided with this kit is sufficient for three individual runs. The volume of diluent and conjugate used for assays using less than a full plate should be scaled down accordingly, keeping the same dilution ratio.
12. Avoid microbial contamination of opened reagents. Salimetrics recommends using opened reagents within one month.

Storage

All components of this kit are stable at 2 - 8°C until the kit's expiration date.

Reagents and Reagent Preparation

1. Anti-Cortisol Coated Plate: A ready-to-use, 96-well microtitre plate pre-coated with monoclonal anti-cortisol antibodies in a resealable foil pouch.
2. Cortisol Standards: Six vials, 500 µL each, labeled A-F, containing cortisol concentrations of 3.000, 1.000, 0.333, 0.111, 0.037, and 0.012 µg/dL, in a synthetic saliva matrix with a non-mercury preservative. (Values in nmol/L are 82.77, 27.59, 9.19, 3.06, 1.02, and 0.33 nmol/L respectively.) Standards are traceable to the NIST standard.
3. Wash Buffer: 100 mL of a 10X phosphate buffered solution containing detergents and a non-mercury preservative. Dilute only the amount needed for current day's use. Discard any leftover reagent. Dilute the wash buffer concentrate 10-fold with room temperature deionized water (100 mL of 10X wash buffer to 900 mL of deionized H_2O). (*Note: If precipitate has formed in the concentrated wash buffer, it may be heated to 40°C for 15 minutes. Cool to room temperature before use in assay.*)
4. Assay Diluent: 60 mL of a phosphate buffered solution containing a pH indicator and a non-mercury preservative.
5. Enzyme Conjugate: 50 µL of a solution of cortisol labeled with horseradish peroxidase. Dilute prior to use with assay diluent.
6. Tetramethylbenzidine (TMB): 25 mL of a non-toxic, ready-to-use solution.
7. Stop Solution: 12.5 mL of a solution of sulfuric acid. Stop solution is provided in powdered form to some customers outside the USA. Reconstitute the powdered stop solution with 12.5 mL of deionized water. Let sit for 10 minutes before use.
8. Non-specific Binding Wells (NSB): These wells do not contain anti-cortisol antibody. In order to support multiple use, a strip of NSB wells is included. They are located in the foil pouch. Wells may be broken off and inserted where needed.

Materials Needed But Not Supplied

- Precision pipette to deliver 15 and 25 µL
- Precision multichannel pipette to deliver 50 µL and 200 µl
- Vortex
- Plate rotator (if unavailable, tap to mix)
- Plate reader with a 450 nm filter
- Log-linear graph paper or computer software for data reduction
- Deionized water
- Reagent reservoirs
- One disposable tube capable of holding 24 mL
- Pipette tips
- Serological pipette to deliver up to 24 mL

Specimen Collection

Donors may collect whole saliva by tilting the head forward, allowing the saliva to pool on the floor of the mouth, then passing the saliva through a straw into a polypropylene vial. Adult samples and samples from children ages 6 and above may also be collected using the Salivettes Oral Swab (SOS), PRN 5001.02. Infant samples may be collected with the Salivettes, PRN 5029, or cotton rolls, PRN 5046.01. Collection protocols are available on request. For accurate results Salivettes and cotton collection materials should be completely saturated before removal. Do not add sodium azide to saliva samples as a preservative. Samples visibly contaminated with blood should be rejected.

Avoid sample collection within 60 minutes after eating a major meal or within 12 hours after consuming alcohol. Routine hygiene is usually patient in daily products can cross-react with anti-cortisol antibodies and cause false results. Acidic or high sugar foods can compromise assay performance by lowering sample pH and initiating bacterial growth. To minimize these factors, rinse mouth thoroughly with water 10 minutes before sample is collected. It is important to record the time and date of specimen collection when samples are obtained due to the diurnal variation in cortisol levels. Samples for Cushing's diagnosis should be collected at 11:00 pm. After collection it is important to keep samples cold, in order to avoid bacterial growth in the specimen. Refrigerate samples within 30 minutes, and freeze at or below -20°C within 4 hours after collection. (Samples may be stored at -20°C or lower for long-term storage.)

Freezing saliva samples will precipitate the mucins. On day of assay, thaw completely, vortex, and centrifuge at 1500 x g (4000 rpm) for 15 minutes. Avoid multiple freeze-thaw cycles. However, if samples have been refrozen, centrifuge again prior to assaying. Samples should be at assay temperature before adding to assay plate. Pipette clear sample into appropriate wells. Particulate matter may interfere with antibody binding, leading to falsely elevated results.

Procedure

Bring all reagents to room temperature. Note: It is important to keep the zip-lock pouch with the plate strips closed until warmed to room temperature as humidity may have an effect on the coated wells. Mix all reagents before use.

Step 1: Determine your plate layout. Here is a suggested layout.

	1	2	3	4	5	6	7	8	9	10	11	12
A	3.000 Std	3.000 Std	C-H	C-H								
B	1.000 Std	1.000 Std	C-L	C-L								
C	0.333 Std	0.333 Std	Unk-1	Unk-1								
D	0.111 Std	0.111 Std	Unk-2	Unk-2								
E	0.037 Std	0.037 Std	Unk-3	Unk-3								
F	0.012 Std	0.012 Std	Unk-4	Unk-4								
G	Zero	Zero	Unk-5	Unk-5								
H	NSB	NSB	Unk-6	Unk-6								

Step 2: Keep the desired number of strips in the strip holder and place the remaining strips back in the foil pouch. If you choose to place non-specific binding wells in H-1, 2, remove strips 1 and 2 from the strip holder and break off the bottom wells. Place the strips back into the strip holder leaving H-1, 2 blank. Break off 2 NSB wells from the strip of NSBs included in the foil pouch. Place in H-1, 2. Alternatively, NSBs may be placed wherever you choose on the plate. Reseal the zip-lock pouch with unused wells and desiccant. Store at 2 - 8°C.

Caution: Extra NSB wells should not be used for determination of standards, controls or unknowns.

Step 3:

- Pipette 24 mL of assay diluent into a disposable tube. Set aside for Step 5.

Step 4:

- Pipette 25 µL of standards, controls, and unknowns into appropriate wells. Standards, controls, and unknowns should be assayed in duplicate.
- Pipette 25 µL of assay diluent into 2 wells to serve as the zero.
- Pipette 25 µL of assay diluent into each NSB well.

Step 5: Make a 1:1000 dilution of the conjugate by adding 25 µL of the conjugate to the 24 mL of assay diluent prepared in Step 3. (Scale down proportionally if not using the entire plate.) Immediately mix the diluted conjugate solution and pipette 200 µL into each well using a multichannel pipette.

Step 6: Mix plate on rotator for 5 minutes at 500 rpm (or tap to mix) and incubate at room temperature for an additional 55 minutes.

Step 7: Wash the plate 4 times with 1X wash buffer. A plate washer is recommended. However, washing may be done by gently squirting wash buffer into each well with a squirt bottle, or by pipetting 300µL of wash buffer into each well, and then discarding the liquid by inverting the plate over a sink. After each wash, the plate should be thoroughly blotted on paper towels before being turned upright. *If using a plate washer, blotting is still recommended after the last wash.*

Step 8: Add 200 µL of TMB solution to each well with a multichannel pipette.

Step 9: Mix on a plate rotator for 5 minutes at 500 rpm (or tap to mix) and incubate the plate in the dark at room temperature for an additional 25 minutes.

Step 10: Add 50 µL of stop solution with a multichannel pipette.

Step 11:

- *Mix on a plate rotator for 3 minutes at 500 rpm (or tap to mix). Caution: Do not mix at speeds over 600 rpm.*
- Wipe off bottom of plate with a water-moistened, lint-free cloth and wipe dry.
- Read in a plate reader at 450 nm. Read plate within 10 minutes of adding stop solution. (Correction at 450 by 630 is desirable.)

Calculations

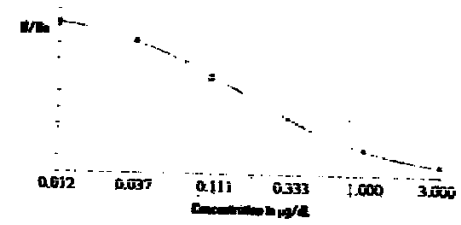
1. Compute the average optical density (OD) for all duplicate wells.
2. Subtract the average OD for the NSB wells from the average OD of the zero, standards, controls, and unknowns.
3. Calculate the percent bound (B/Bo) for each standard, control, and unknown by dividing the average OD (B) by the average OD for the zero (Bo).
4. Determine the concentrations of the controls and unknowns by interpolation using software capable of logistics. We recommend using a 4-parameter sigmoid minus curve fit.

Typical Results

The following charts and graphs are for illustration only and should not be used to calculate results from another assay.

Well	Sample	Average OD	B	B/Bo	Cortisol (µg/dL)
A1,A2	S1	0.894	0.971	0.048	3.000
B1,B2	S2	0.292	0.213	0.145	1.000
C1,C2	S3	0.526	0.501	0.340	0.333
D1,D2	S4	0.897	0.874	0.593	0.111
E1,E2	S5	1.219	1.196	0.812	0.037
F1,F2	S6	1.379	1.356	0.921	0.012
G1,G2	Bo	1.496	1.473	NA	NA
H1,H2	NSB	0.023	NA	NA	NA

Example: Cortisol 4-Parameter Sigmoid Minus Curve Fit



Material Safety Data*

Hazardous Ingredients
Liquid stop solution is caustic; use with care. *Note: Stop solution in powdered form is not sulfuric acid-based and is mildly corrosive.*
We recommend the procedures listed below for all kit reagents. Specific kit component MSDS sheets are available from Salimetrics upon request.

Handling
Follow good laboratory procedures when handling kit reagents. Laboratory coats, gloves, and safety goggles are recommended. Wipe up spills using standard absorbent materials while wearing protective clothing. Follow local regulations for disposal.

Emergency Exposure Measures
In case of contact, immediately wash skin or flush eyes with water for 15 minutes. Remove contaminated clothing. If inhaled, remove individual to fresh air. If individual experiences difficulty breathing, give oxygen and call a physician.

*The above information is believed to be accurate but is not all-inclusive. This information should only be used as a guide. Salimetrics shall not be liable for accidents or damage resulting from contact with reagents.

HS Cortisol EIA Assay Performance Characteristics

Recovery: Six saliva samples containing different levels of endogenous cortisol were spiked with known quantities of cortisol and assayed.

Sample	Endogenous (µg/dL)	Added (µg/dL)	Expected (µg/dL)	Observed (µg/dL)	Recovery (%)
1	0.088	2.000	2.088	2.176	104.2
2	0.077	0.300	0.377	0.380	100.8
3	0.062	0.011	0.073	0.071	97.3
4	0.056	2.500	2.556	2.720	106.1
5	0.200	0.330	0.530	0.508	95.6
6	0.086	0.811	0.897	0.854	94.9

Precision:

1. The intra-assay precision was determined from the mean of 14 (low) and 18 (high) replicates each.

Sample	N	Mean (µg/dL)	Standard Deviation (µg/dL)	Coefficient of Variation (%)
Level 1	18	0.990	0.033	3.35
Level 2	14	0.107	0.004	3.65

2. The inter-assay precision was determined from the mean of average duplicates for 12 separate runs.

Sample	N	Mean (µg/dL)	Standard Deviation (µg/dL)	Coefficient of Variation (%)
Level 1	12	1.020	0.038	3.75
Level 2	12	0.101	0.006	6.41

Linearity of Dilution: Two saliva samples were diluted with assay diluent and assayed.

Sample	Dilution Factor	Expected (µg/dL)	Observed (µg/dL)	Recovery (%)
1			2.176	
	1:2	1.088	1.000	91.9
	1:4	0.544	0.503	92.5
	1:8	0.272	0.233	85.7
	1:16	0.136	0.109	80.1
2			0.508	
	1:2	0.254	0.247	97.2
	1:4	0.127	0.118	92.9
	1:8	0.064	0.058	90.6
	1:16	0.032	0.031	96.9

Sensitivity: The lower limit of sensitivity was determined by interpolating the mean minus 2 SDs for 10 sets of duplicates at 0 µg/dL standard. The minimal concentration of cortisol that can be distinguished from 0 is < 0.003 µg/dL.

Correlation with Serum: The correlation between serum and saliva cortisol was determined by assaying 49 matched samples using the Diagnostic Systems Laboratories' serum Cortisol EIA and the Salimetrics HS Salivary Cortisol EIA.

The correlation between saliva and serum was highly significant, r (47) = 0.91, p < 0.0001.

Expanded Range High Sensitivity Salivary Cortisol EIA Kit Insert,
Cat. # 1-3002/1-3012, 1-3002-5/1-3012-5

Specificity of Antiserum

Compound	Spiked Concentration (ng/mL)	% Cross-reactivity in ER HS Salivary Cortisol EIA
Prednisolone	100	0.568
Prednisone	1000	ND
Cortisone	1000	0.130
11-Deoxycortisol	500	0.156
21-Deoxycortisol	1000	0.041
17 α-Hydroxyprogesterone	1000	ND
Dexamethasone	1000	19.2
Triamcinolone	1000	0.086
Corticosterone	10,000	0.214
Progesterone	1000	0.015
17β - Estradiol	10	ND
DHEA	10,000	ND
Testosterone	10,000	0.006
Transferrin	66,000	ND
Aldosterone	10,000	ND

ND = None detected (<0.004)

Salivary Cortisol Expected Ranges
Each laboratory should establish its own range of expected values. The following values have been reported for salivary cortisol.

Group	Number	Overall Range in µg/dL
Children, neonatal	275	ND – 2.437
Children, age 6 months	163	ND – 2.294

Group	Number	AM Range in µg/dL	PM Range in µg/dL
Children, ages 2.5-5.5	182	0.051 - 0.643	0.035 - 0.483
Children, ages 8-11	285	0.094 - 0.859	ND - 0.215
Adolescents, ages 12-18	405	0.021 - 0.883	ND - 0.259
Adult males, ages 21-30	26	0.112 - 0.743	ND - 0.308
Adult females, ages 21-30	30	0.272 - 1.348	ND - 0.359
Adult males, ages 31-50	67	0.122 - 1.551	ND - 0.359
Adult females, ages 31-50	55	0.094 - 1.515	ND - 0.181
Adult males, ages 51-70	26	0.122 - 0.812	ND - 0.326
Adult females, ages 51-70	21	0.149 - 0.739	0.002 - 0.254
All adults	182	0.094 - 1.551	ND - 0.359

Group	Number	2000h (µg/dL)
Normal subjects	19	0.007 – 0.115
Cushing's subjects	21	0.130 – 2.972

ND = None detected
Expected ranges for neonates to 5.5 years were derived using the Salimetrics Salivary Cortisol Immunoassay Kit.
Expected ranges for 8 to 18 years were reported from an unpublished manuscript, Pennsylvania State University's Behavioral Endocrinology Laboratory. Adult ranges were obtained from published literature (22).

References

1. Schwartz, E.B., Granger, D.A., Susman, E.J., Gunnar, M.R., & Laird, B. (1998). Assessing salivary cortisol in studies of child development. *Child Development, 69*, 1503-1513.
2. Chard, T. (1990). *An introduction to radioimmunoassay and related techniques.* Amsterdam: Elsevier.
3. Kivlighan, K. T., Granger, D. A., Schwartz, E. B., Nelson, V., & Curran, M. (2004). Quantifying blood leakage into the oral mucosa and its effects on the measurement of cortisol, dehydroepiandrosterone, and testosterone in saliva. *Hormones and Behavior, 46*, 39-46.
4. Schwartz, E., & Granger, D. A. (2004). Transferrin enzyme immunoassay for quantitative monitoring of blood contamination in saliva. *Clinical Chemistry, 50*, 654-656.

Seller's Limited Warranty
"Seller warrants that all goods sold hereunder will be free from defects in material and workmanship. Upon prompt notice by Buyer of any claimed defect, which notice must be sent within thirty (30) days from date such defect is first discovered and within three months from the date of shipment, Seller shall, at its option, either repair or replace the product that is proved to Seller's satisfaction to be defective. All claims should be submitted in writing. This warranty does not cover any damage due to accident, misuse, negligence, or abnormal use. Liability in all cases, will be limited to the purchased cost of the kit.

It is expressly agreed that this limited warranty shall be in lieu of all warranties of fitness and in lieu of the warranty of merchantability. Seller shall not be liable for any incidental or consequential damages that arise out of the installation, use or operation of Seller's product or out of the breach of any express or implied warranties."

Appendix A
Officer Basic Leadership Course Description

Leadership Development Branch Mission for the Officer Basic Leadership Course:
The Leader Development Branch (LDB) trains initial entry Army Medical Department (AMEDD) officers for success at their first assignment and to survive in the Contemporary Operating Environment (COE). The Officer Basic Leader Course (OBLC) training occurs at Fort Sam Houston and Camp Bullis, Texas, and stresses leadership training, the fundamentals of AMEDD health service support doctrine, Army administrative and operational overviews, and fundamental survival skills.

LDB Goals for OBLC:
– Improve the officer's ability to analyze & solve military problems
– Improve the officer's ability to communicate, interact and coordinate as a staff member
– Improve the officers understanding of Army organizations, operations, and procedures
– Develop the officers soldier/leader skills and building regimental pride

AMEDD Officer Basic Leader Course (OBLC)
Length: 7 Weeks (+ 1-5 weeks additional Track Training as determined by Corps Branch)
Purpose: To provide performance-oriented training to newly commissioned Active Duty AMEDD officers in the following Corps: MC, AN, SP (minus 65D), DC, VC, and MS (minus 70B/67J). A 7 week core course covering general subjects and basic soldier/leader skills required to execute field training. The course consists of 3 Field Training Exercises (Individual, Collective, and AMEDD Skills) and addition track specific training focused on each AMEDD Branch. This course will provide the newly commissioned AMEDD officer with the basic skills and knowledge necessary to effectively function in an AMEDD unit.

This course is designed to instruct you in the fundamentals of being a Competent, Confident and Agile leader in today's Army. It will greatly assist you in making your transition into the Army successful, and prepare you for your first duty assignment. Your focus here at the AMEDD Center & School will be discipline, teamwork, warrior leader skills, tactical medical doctrine, and learning the principles behind becoming an effective leader and an AMEDD officer.

Execution: 5 classes per year

Accessed July 10, 2008 online at: http://www.cs.amedd.army.mil/obc/ .

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Appendix B
Filter Paper Collection Method for Salivary Cortisol

Saliva samples for salivary cortisol determinations will be collected by a filter paper method as described by Neu, Goldstein, Gao, et. al., 2007. This collection procedure is non-invasive and minimally demanding for subjects. Subjects will be asked to avoid caffeine on the morning of the test and to avoid drinking anything for several minutes prior to each salivary collection. For filter paper collection, subjects will be instructed to place the filter paper in their mouths until saturated. Generally, this takes no longer than 1 minute. After the filter paper is removed from the subject's mouth, the furthest extent of the fluid migration on the filter will be marked with a pencil. The top portion of the filter will be pre-labeled with the study subject ID number, date and time of collection. Filter papers will be air dried and then placed individually in a plastic bag to prevent cross contamination of specimens. Determination of salivary cortisol will be done by the School of Nursing Center for Biobehavioral Clinical Research Core Laboratory using commercially available ELISA assays.

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Appendix C
Demographic Factors Survey
(adapted from the Well-Being and Retention of Officers in the Army Nurse Corps Survey; U.S. Army Research Institute, 2007, with additional study-specific items)

Your Gender:
___ Male
___ Female

Your Age:
___ Under 20 years of age
___ 20-24 years of age
___ 25-29 years of age
___ 30-34 years of age
___ 35-39 years of age
___ 40-44 years of age
___ 45-49 years of age
___ 50 years of age or older

Are you of Hispanic, Latino, or Spanish ancestry of any race (mark all that apply):
___ No, not of Hispanic, Latino, or Spanish ancestry
___ Yes, Mexican, Mexican American, or Chicano
___ Yes, Puerto Rican
___ Yes, Cuban
___ Yes, other Hispanic, Latino, or Spanish ancestry

Your Race:
___ American Indian or Alaskan Native (eg. Eskimo, Aleut)
___ Asian (eg. Asian Indian, Chinese, Filipino, Japanese, Korean, Vietnamese)
___ Black or African American
___ Native Hawaiian or other Pacific Islander (eg., Samoan, Guamanian, Chamorro)
___ White or Caucasian

Your Highest Level of Education Completed:
___ Associate's degree
___ Bachelor's degree
___ One year or more of graduate credit, but no graduate degree
___ Master's degree
___ PhD
Other, please specify: _____

Your Marital Status:
___ Single and never married
___ Married
___ Separated
___ Divorced
___ Widowed

How many dependent children do you have (for whom you provide over half of their support?)

___ None
___ One
___ Two
___ Three
___ Four or more

How many years of Active Federal Military Service (AFMS) and/or Reserve service have you completed:

Total years Active component: _____
Total years Reserve component: _____

Your current rank:

___ 2LT
___ 1LT
___ CPT
___ MAJ
___ LTC
___ COL
Other (please specify): _____

How many times have you been deployed?

Total number of times: _____

How many total months have you been deployed?

Total number of months: _____

Where were you deployed? (Mark all that apply.)

___ Afghanistan
___ Kuwait
___ Iraq
___ South Korea
___ Elsewhere in Asia
___ Europe
___ Another OCONUS site
___ CONUS site

Did you deploy to a combat zone in a medical or nursing MOS (military occupational specialty)? If so, what and how many total months were you deployed in a medical or nursing MOS?

___ Yes; _____ total number of months deployed in medical or nursing MOS
___ No

What is your current primary Area of Concentration (AOC)?

___ 66B-Army Public Health Nurse
___ 66C-Psychiatric/Mental Health Nurse
___ 66E-Perioperative Nurse
___ 66F-Nurse Anesthetist
___ 66G-Obstetrics and Gynecology
___ 66H-Medical-Surgical Nurse
___ 66N-Generalist Nurse
___ 66P-Family Nurse Practitioner

Other (please specify AOC name and alphanumeric designation): _____

Please indicate any Additional Skill Identifier (ASIs) that you currently hold: (Mark all that apply.)

___ Not applicable, do not have one
___ 7T Clinical Nurse Specialist
___ 8A Critical Care Nursing
___ 8D Midwifery
___ 8J Infection Control
___ M5 Emergency Room Nurse
Other (please specify ASI name and alphanumeric designation): _____

Please indicate any previous civilian medical or nursing experience and number of years in that role (mark all that apply):

___ Not applicable
___ EMT (emergency medical technician); ___ years
___ LPN (licensed practical nurse); ___ years
___ RN (registered nurse); ___ years
___ APN (advanced nurse practitioner); ___ years
___ 91 B (combat medic); ___ years
___ 91 C (Army LPN); ___ years
___ 91 W (Army EMT/paramedic); ___ years
___ 66 series (Army nurse; ___ years
Other (please specify AOC name and alphanumeric designation): _____

Please indicate any previous civilian medical or nursing *specialty* experience and indicate the number of years in that specialty (mark all that apply):

___ Operating room; _____ years
___ Emergency room; _____ years
___ Medical-surgical; _____ years
___ Critical care; _____ years
Other (please specify specialty): _____; _____ years

Your Pre-commissioning source:

___ Officer Candidate School
___ ROTC scholarship
___ ROTC non-scholarship
___ United States Military Academy
___ Direct Appointment
Other (please specify): _____

End of Demographic Survey

Appendix

The Life Experiences Survey

Listed below are a number of events which sometimes bring about change in the lives of those who experience them and which sometimes require readjustment. Please check those events which you have experienced in the recent past and indicate the time period during which you have experienced each event. Be sure that all check marks are directly across from the items they correspond to.

Also, for each item checked below, please indicate the extent to which you viewed the event as having either a positive or negative impact on your life at the time the event occurred. That is, indicate the *type and extent of impact that the event had.* A rating of −3 would indicate an extremely negative impact. A rating of 0 suggests no impact either positive or negative. A rating of +3 would indicate an extremely positive impact.

Section 1

	6 mos or less	7 mos to 1 yr	extremely negative	moderately negative	mildly negative	no impact	mildly positive	moderately positive	extremely positive
1. Marriage			−3	−2	−1	0	+1	+2	+3
2. Detention in jail or comparable institution			−3	−2	−1	0	+1	+2	+3
3. Death of spouse			−3	−2	−1	0	+1	+2	+3
4. Major change in sleeping habits (much more or much less sleep)			−3	−2	−1	0	+1	+2	+3

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	0 to 6 mo	7 mo to 1 yr	extremely negative	moderately negative	somewhat negative	no impact	slightly positive	moderately positive	extremely positive
5. Death of close family member:									
a. mother			−3	−2	−1	0	+1	+2	+3
b. father			−3	−2	−1	0	+1	+2	+3
c. brother			−3	−2	−1	0	+1	+2	+3
d. sister			−3	−2	−1	0	+1	+2	+3
e. grandmother			−3	−2	−1	0	+1	+2	+3
f. grandfather			−3	−2	−1	0	+1	+2	+3
g. other (specify)			−3	−2	−1	0	+1	+2	+3
6. Major change in eating habits (much more or much less food intake)			−3	−2	−1	0	+1	+2	+3
7. Foreclosure on mortgage or loan			−3	−2	−1	0	+1	+2	+3
8. Death of close friend			−3	−2	−1	0	+1	+2	+3
9. Outstanding personal achievement			−3	−2	−1	0	+1	+2	+3
10. Minor law violations (traffic tickets, disturbing the peace, etc.)			−3	−2	−1	0	+1	+2	+3
11. *Male:* Wife/girlfriend's pregnancy			−3	−2	−1	0	+1	+2	+3
12. *Female:* Pregnancy			−3	−2	−1	0	+1	+2	+3
13. Changed work situation (different work responsibility, major change in working conditions, working hours, etc.)			−3	−2	−1	0	+1	+2	+3
14. New job			−3	−2	−1	0	+1	+2	+3
15. Serious illness or injury of close family member:									
a. father			−3	−2	−1	0	+1	+2	+3
b. mother			−3	−2	−1	0	+1	+2	+3
c. sister			−3	−2	−1	0	+1	+2	+3
d. brother			−3	−2	−1	0	+1	+2	+3
e. grandfather			−3	−2	−1	0	+1	+2	+3
f. grandmother			−3	−2	−1	0	+1	+2	+3
g. spouse			−3	−2	−1	0	+1	+2	+3
h. other (specify)			−3	−2	−1	0	+1	+2	+3
16. Sexual difficulties			−3	−2	−1	0	+1	+2	+3
17. Trouble with employer (in danger of losing job, being suspended, demoted, etc.)			−3	−2	−1	0	+1	+2	+3
18. Trouble with in-laws			−3	−2	−1	0	+1	+2	+3
19. Major change in financial status (a lot better off or a lot worse off)			−3	−2	−1	0	+1	+2	+3
20. Major change in closeness of family members (increased or decreased closeness)			−3	−2	−1	0	+1	+2	+3
21. Gaining a new family member (through birth, adoption, family member moving in, etc.)			−3	−2	−1	0	+1	+2	+3
22. Change of residence			−3	−2	−1	0	+1	+2	+3
23. Marital separation from mate (due to conflict)			−3	−2	−1	0	+1	+2	+3
24. Major change in church activities (increased or decreased attendance)			−3	−2	−1	0	+1	+2	+3

V. 1978, Sarason
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	0 to 6 mo	7 mo to 1 yr	extremely negative	moderately negative	somewhat negative	no impact	slightly positive	moderately positive	extremely positive
25. Marital reconciliation with mate			−3	−2	−1	0	+1	+2	+3
26. Major change in number of arguments with spouse (a lot more or a lot less arguments)			−3	−2	−1	0	+1	+2	+3
27. *Married male*: Change in wife's work outside the home (beginning work, ceasing work, changing to a new job, etc.)			−3	−2	−1	0	+1	+2	+3
28. *Married female*: Change in husband's work (loss of job, beginning new job, retirement, etc.)			−3	−2	−1	0	+1	+2	+3
29. Major change in usual type and/or amount of recreation			−3	−2	−1	0	+1	+2	+3
30. Borrowing more than $10,000 (buying home, business, etc.)			−3	−2	−1	0	+1	+2	+3
31. Borrowing less than $10,000 (buying car, TV, getting school loan, etc.)			−3	−2	−1	0	+1	+2	+3
32. Being fired from job			−3	−2	−1	0	+1	+2	+3
33. *Male*: Wife/girlfriend having abortion			−3	−2	−1	0	+1	+2	+3
34. *Female*: Having abortion			−3	−2	−1	0	+1	+2	+3
35. Major personal illness or injury			−3	−2	−1	0	+1	+2	+3
36. Major change in social activities, e.g., parties, movies, visiting (increased or decreased participation)			−3	−2	−1	0	+1	+2	+3
37. Major change in living conditions of family (building new home, remodeling, deterioration of home, neighborhood, etc.)			−3	−2	−1	0	+1	+2	+3
38. Divorce			−3	−2	−1	0	+1	+2	+3
39. Serious injury or illness of close friend			−3	−2	−1	0	+1	+2	+3
40. Retirement from work			−3	−2	−1	0	+1	+2	+3
41. Son or daughter leaving home (due to marriage, college, etc.)			−3	−2	−1	0	+1	+2	+3
42. Ending of formal schooling			−3	−2	−1	0	+1	+2	+3
43. Separation from spouse (due to work, travel, etc.)			−3	−2	−1	0	+1	+2	+3
44. Engagement			−3	−2	−1	0	+1	+2	+3
45. Breaking up with boyfriend/girlfriend			−3	−2	−1	0	+1	+2	+3
46. Leaving home for the first time			−3	−2	−1	0	+1	+2	+3
47. Reconciliation with boyfriend/girlfriend			−3	−2	−1	0	+1	+2	+3
Other recent experiences which have had an impact on your life. List and rate.									
48. _____			−3	−2	−1	0	+1	+2	+3
49. _____			−3	−2	−1	0	+1	+2	+3
50. _____			−3	−2	−1	0	+1	+2	+3

V. 1978, Sarason
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	0 to 6 mo	7 mo to 1 yr	extremely negative	moderately negative	somewhat negative	no impact	slightly positive	moderately positive	extremely positive
Section I: Student Only									
51. Beginning a new school experience at a higher academic level (college, graduate school, professional school, etc.)			−3	−2	−1	0	+1	+2	+3
52. Changing to a new school at higher academic level (undergraduate, graduate, etc.)			−3	−2	−1	0	+1	+2	+3
53. Academic probation			−3	−2	−1	0	+1	+2	+3
54. Being dismissed from dormitory or other residence			−3	−2	−1	0	+1	+2	+3
55. Failing an important exam			−3	−2	−1	0	+1	+2	+3
56. Changing a major			−3	−2	−1	0	+1	+2	+3
57. Failing a course			−3	−2	−1	0	+1	+2	+3
58. Dropping a course			−3	−2	−1	0	+1	+2	+3
59. Joining a fraternity/sorority			−3	−2	−1	0	+1	+2	+3
60. Financial problems concerning school (in danger of not having sufficient money to continue)			−3	−2	−1	0	+1	+2	+3

Received June 23, 1977 ■

V. 1978, Sarason
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PSS-14

INSTRUCTIONS:

The questions in this scale ask you about your feelings and thoughts during THE LAST MONTH. In each case, you will be asked to indicate your response by placing an "X" over the circle representing HOW OFTEN you felt or thought a certain way. Although some of the questions are similar, there are differences between them and you should treat each one as a separate question. The best approach is to answer fairly quickly. That is, don't try to count up the number of times you felt a particular way, but rather indicate the alternative that seems like a reasonable estimate.

	Never	Almost Never	Sometimes	Fairly Often	Very Often
	1	2	3	4	5
1. In the last month, how often have you been upset because of something that happened unexpectedly?	O	O	O	O	O
2. In the last month, how often have you felt that you were unable to control the important things in your life?	O	O	O	O	O
3. In the last month, how often have you felt nervous and "stressed"?	O	O	O	O	O
4. In the last month, how often have you dealt successfully with day to day problems and annoyances?	O	O	O	O	O
5. In the last month, how often have you felt that you were effectively coping with important changes that were occurring in your life?	O	O	O	O	O
6. In the last month, how often have you felt confident about your ability to handle your personal problems?	O	O	O	O	O
7. In the last month, how often have you felt that things were going your way?	O	O	O	O	O
8. In the last month, how often have you found that you could not cope with all the things that you had to do?	O	O	O	O	O
9. In the last month, how often have you been able to control irritations in your life?	O	O	O	O	O
10. In the last month, how often have you felt that you were on top of things?	O	O	O	O	O

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PSS-14, 1 of 2

PSS-14

	Never	Almost Never	Sometimes	Fairly Often	Very Often
	1	2	3	4	5
11. In the last month, how often have you been angered because of things that happened that were outside of your control?	O	O	O	O	O
12. In the last month, how often have you found yourself thinking about things that you have to accomplish?	O	O	O	O	O
13. In the last month, how often have you been able to control the way you spend your time?	O	O	O	O	O
14. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?	O	O	O	O	O

IMPACT OF EVENT SCALE-REVISED

Instructions: The following is a list of difficulties people sometimes have after stressful life events. Please read each item, and then indicate how distressing each difficulty has been for you during the past 7 days with respect to the disaster. How much were you distressed or bothered by these difficulties?

		Not at all	A little bit	Moderately	Quite a bit	Extremely
1	Any reminder brought back feelings about it.	0	1	2	3	4
2	I had trouble staying asleep.	0	1	2	3	4
3	Other things kept making me think about it.	0	1	2	3	4
4	I felt irritable and angry.	0	1	2	3	4
5	I avoided letting myself get upset when I thought about it or was reminded of it.	0	1	2	3	4
6	I thought about it when I didn't mean to.	0	1	2	3	4
7	I felt as if it hadn't happened or wasn't real.	0	1	2	3	4
8	I stayed away from reminders about it.	0	1	2	3	4
9	Pictures about it popped into my mind.	0	1	2	3	4
10	I was jumpy and easily startled.	0	1	2	3	4
11	I tried not to think about it.	0	1	2	3	4
12	I was aware that I still had a lot of feelings about it, but I didn't deal with them.	0	1	2	3	4
13	My feelings about it were kind of numb.	0	1	2	3	4
14	I found myself acting or feeling like I was back at that time.	0	1	2	3	4
15	I had trouble falling asleep.	0	1	2	3	4
16	I had waves of strong feelings about it.	0	1	2	3	4
17	I tried to remove it from my memory.	0	1	2	3	4
18	I had trouble concentrating.	0	1	2	3	4
19	Reminders of it caused me to have physical reactions, such as sweating, trouble breathing, nausea, or a pounding heart.	0	1	2	3	4
20	I had dreams about it.	0	1	2	3	4
21	I felt watchful and on guard.	0	1	2	3	4
22	I tried not to talk about it.	0	1	2	3	4

V. 1997, Weiss Thurman
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VCU Memo

Office of Research Subjects Protection
Bio-Tech Research Park, Building 1
800 E. Leigh St., Ste.#114
P.O. Box 980568
Richmond, Virginia 23298-0568

DATE: August 18, 2008

TO: Mary Jo Grap, PhD, RN, FAAN
School of Nursing
Box 980567

FROM: Andrea Hastillo, MD Andrea Hastillo
Chairperson, VCU IRB Panel C AUG 19.2008
Box 980568

RE: VCU IRB #: HM11746
Title: Exploring the Stress response in New Army Nurses

On August 18, 2008, the following research study was approved by expedited review according to 45 CFR 46.110 Category 3. This approval reflects the revisions received in the Office of Research Subjects Protection on August 18, 2008. This approval includes the following items reviewed by this Panel:

RESEARCH APPLICATION/PROPOSAL: None

PROTOCOL: Exploring the Stress response in New Army Nurses (v. 7/16/08)-stamped received 7/25/08
- OTTO Appendix A-OBLC description (v.8/12/08)-stamped received 8/18/08
- OTTO Appendix B-saliv cort filter paper (v. 8/12/08)-stamped received 8/18/08
- OTTO Appendix C-demographic survey (v. 8/12/08)-stamped received 8/18/08
- OTTO Appendix D-LES (v.1978, Sarason)-stamped received 8/18/08
- OTTO Appendix E- PSS-14 (v.8/12/08)-stamped received 8/18/08
- OTTO Appendix F-IES-R (v. 1997, Weiss & Marmar(-stamped received 8/18/08

CONSENT/ASSENT:
- Research Subject Information and Consent Form (v. 8/12/08)-stamped received 8/18/08, 5 pages

ADDITIONAL DOCUMENTS:
- OTTO Appendix G- Study Announcement Flyer (v. 7/16/08)-stamped received 8/18/08, 1 page

This approval expires on July 31, 2009. Federal Regulations/VCU Policy and Procedures require continuing review prior to continuation of approval past that date. Continuing Review report forms will be mailed to you prior to the scheduled review.

The Primary Reviewer assigned to your research study is Valentina Lucas, RN, MS. If you have any questions, please contact Valentina Lucas at vslucas@vcu.edu and 828-3049; or you may contact Nichole Haywood, IRB Coordinator, VCU Office of Research Subjects Protection, at nsrichar@hsc.vcu.edu or 827-1446.

Attachment – Conditions of Approval

Conditions of Approval:

In order to comply with federal regulations, industry standards, and the terms of this approval, the investigator must *(as applicable):*

1. **Conduct the research as described in and required by the Protocol.**

2. **Obtain informed consent from all subjects without coercion or undue influence, and provide the potential subject sufficient opportunity to consider whether or not to participate (unless Waiver of Consent is specifically approved or research is exempt).**

3. **Document informed consent using only the most recently dated consent form bearing the VCU IRB "APPROVED" stamp (unless Waiver of Consent is specifically approved).**

4. **Provide non-English speaking patients with a translation of the approved Consent Form in the research participant's first language. The Panel must approve the translated version.**

5. **Obtain prior approval from VCU IRB before implementing any changes whatsoever in the approved protocol or consent form, unless such changes are necessary to protect the safety of human research participants (e.g., permanent/temporary change of PI, addition of performance/collaborative sites, request to include newly incarcerated participants or participants that are wards of the state, addition/deletion of participant groups, etc.). Any departure from these approved documents must be reported to the VCU IRB immediately as an Unanticipated Problem (see #7).**

6. **Monitor all problems (anticipated and unanticipated) associated with risk to research participants or others.**

7. **Report Unanticipated Problems (UPs), including protocol deviations, following the VCU IRB requirements and timelines detailed in VCU IRB WPP VIII-7):**

8. **Obtain prior approval from the VCU IRB before use of any advertisement or other material for recruitment of research participants.**

9. **Promptly report and/or respond to all inquiries by the VCU IRB concerning the conduct of the approved research when so requested.**

10. **All protocols that administer acute medical treatment to human research participants must have an emergency preparedness plan. Please refer to VCU guidance on http://www.research.vcu.edu/irb/guidance.htm.**

11. **The VCU IRBs operate under the regulatory authorities as described within:**
    a) **U.S. Department of Health and Human Services Title 45 CFR 46, Subparts A, B, C, and D (for all research, regardless of source of funding) and related guidance documents.**
    b) **U.S. Food and Drug Administration Chapter I of Title 21 CFR 50 and 56 (for FDA regulated research only) and related guidance documents.**
    c) **Commonwealth of Virginia Code of Virginia 32.1 Chapter 5,1 Human Research (for all research).**

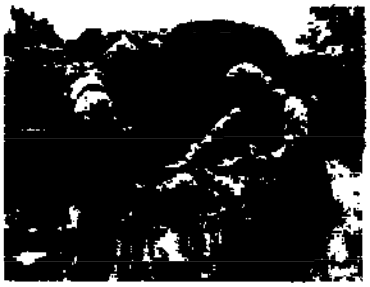
010507

YOUR PARTICIPATION IS REQUESTED

We are seeking volunteers for a research study on describing stress in new Army nurses. The effects of exposure to the stressors of combat have been shown to have physical and psychological consequences including post traumatic stress disorder (PTSD), depression, and anxiety, as well as other health outcomes, both acute and chronic. While overall stress in the military has been studied, studies of stress in military nursing in the combat zone, for the most part, have been limited to studies of military nurses who served in Vietnam. This study's researchers seek to understand the stress process in new Army nurses by looking more closely at collectors related to stress including biological, demographic, environmental, and psychological factors. This study will provide an initial opportunity to describe the relationships among these factors to better understand the stress response in new Army nurses. This information will also help us to understand stress in Army nurses throughout their Army nursing careers and could be helpful in understanding which coping and treatment interventions may help to alleviate stress throughout Army nurses' careers.

Who Can Participate?

All Army nurses attending the current OBLC class who are not pregnant or who do not think they will become pregnant during this OBLC class. Participants must be able to read and write in English, complete several brief surveys and be willing to provide saliva samples throughout OBLC.



Study Location

Participants will be able to complete surveys and collect saliva samples at their own convenience during specified timeframes during OBLC at Ft. Sam Houston and Camp Bullis.

What is Required of Participants?

Participants will be asked to sign a consent form after their questions about the study have been answered and after they understand what will be required for participation. Participants will complete several short surveys and collect several saliva specimens at four different times during OBLC:

1) one day during the first week of OBLC,
2) one day during the convoy training exercise at Camp Bullis,
3) one day during the AMEDD training exercise at Camp Bullis, and
4) one day during the last week of OBLC.

It will take approximately one hour of your time over the course of OBLC to complete these short surveys and collect saliva specimens.

ALL POTENTIAL PARTICIPANTS WILL RECEIVE A COMPLIMENTARY ARMY NURSE CORPS PEN

Who is Conducting this Study?

CPT Laureen Otto, MS RN is a doctoral nursing student at the School of Nursing, Virginia Commonwealth University in Richmond, Virginia.

Mary Jo Gray, PhD RN FAAN is a professor and nurse researcher at the School of Nursing, Virginia Commonwealth University.

Whom may I contact for more information about this study?

CPT Laureen Otto
Cell phone: 804-366-4041
AKO: Laureen.Otto@us.army.mil

v. 2008 07 14

OFFICE OF RESEARCH SUBJECTS PROTECTION

VCU IRB 8-18-08
APPROVED

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: EXPLORING THE STRESS RESPONSE IN NEW ARMY NURSES

VCU IRB PROTOCOL NUMBER: HM11746

INVESTIGATOR: MARY JO GRAP, PI; LAUREEN A. OTTO, STUDENT INVESTIGATOR

This consent form may contain words that you do not understand. Please ask the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

In this consent form, "you" always refers to the subject. If you are a legally authorized representative, please remember that "you" refers to the study subject.

PURPOSE OF THE STUDY

The purpose of this dissertation research is to describe relationships among biological, demographic, environmental and psychological factors of stress in new Army nurses as they begin their Army nursing careers. This study will focus on potentially stressful experiences for new Army nurses during the Officer Basic Leadership Course (OBLC), where nearly all new Army nurses begin their Army nursing careers and will provide useful baseline information about the stress response.

DESCRIPTION OF THE STUDY

Baseline descriptive information about stress in new Army nurses is critical in understanding stress experienced by Army nurses throughout their Army nursing careers. This study could dramatically impact retention efforts of Army nurses as the Army uses this information to tailor effective coping and treatment strategies at different points throughout an Army nurse's career.

Your participation in this study will last up to an hour of your time over the course of OBLC. The time required to complete study materials is approximately 25-30 minutes during the first week of OBLC, Week 5 and Week 6 study materials each will take approximately 9-13 minutes, and Week 8 study materials will take is approximately 12-16 minutes for a total of approximately one hour over the course of OBLC. Approximately 100 subjects will participate in this study.

Your participation in this study will contribute to a greater understanding of the baseline factors of stress in new Army nurses and how these factors may be related to stress experiences thoughout an Army nurse's career.

VL/MH/8-18-08
APPROVED

PROCEDURES

If you decide to be in this research study, you will be asked to sign this consent form after you have had all your questions answered. This study presents no more than minimal risk to study participants. If you decide to participate in this research study, your participation will occur over four time points during OBLC.

Week 1. During the first week of OBLC, research packet materials will include the first day's saliva collection materials (4 samples total), a demographic questionnaire, a Life Experiences Survey, a Perceived Stress Scale an Impact of Event Scale all to be completed on one day of your choosing during the first week of OBLC but no later than seven days after the brief description of the study that was provided by the study investigator. You will be instructed to deposit completed Week 1 packets at a designated collection point as instructed during the informational session by the study investigator. The packet will consist of a plain, unlabeled envelope.

Week 5. During Week 5 of OBLC, packet materials will include one day's worth of saliva collection materials (4 samples total) and one Impact of Event Scale. The identified stressful event for this IES-R is "convoy training exercise day." The saliva samples will be collected on a "convoy training day" during the field training exercise at Camp Bullis and the Impact of Event Scale will be completed no later than seven days after "convoy training day". You will be instructed to deposit Week 5 packets at a designated collection point as was instructed during the informational session during the first week of OBLC. The packet will consist of a plain, unlabeled envelope.

Week 6. During Week 6 of OBLC, packet materials will include one day's worth of saliva collection materials (4 samples total) and one Impact of Event Scale. The saliva samples will be collected on a "mass casualty triage training exercise day" during the field training exercise at Camp Bullis and the Impact of Event Scale will be completed no later than seven days after "mass casualty triage training exercise day". You will be instructed to deposit Week 5 packets at a designated collection point as was instructed during the informational session during the first week of OBLC. The packet will consist of a plain, unlabeled envelope.

Week 8. During Week 8 of OBLC, packet materials will include one day's worth of saliva collection materials (4 samples total), one Perceived Stress Scale and one Impact of Event Scale to be completed on one day of your choosing during the last week of OBLC. You will be instructed to deposit completed Week 1 packets at a designated collection point as instructed during the informational session by the study investigator. The packet will consist of a plain, unlabeled envelope.

RISKS AND DISCOMFORTS

This study presents no more than minimal risk to study participants. Subjects may experience some distress in recalling stressful events when completing the surveys. Participants may be inconvenienced by providing saliva samples and completing the surveys. The time required to complete, for example, Week 1 study materials is approximately 25-30 minutes, Week 5 and Week 6 study materials each is approximately 9-13 minutes, and Week 8 study materials is approximately 12-16 minutes for a total of approximately one hour over the course of OBLC.

BENEFITS TO YOU AND OTHERS

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There is no guarantee that you will receive any medical benefits from being in this study. The minimal risk to participants in this research study is reasonable given the benefit of learning about the baseline factors of stress in new Army nurses and how these factors may be related to stress experiences throughout an Army nurse's career. The investigative team on this study will not be receiving any money for the conduct of this study.

COSTS
There are no monetary charges for participation in this research study.

PAYMENT FOR PARTICIPATION
All potential participants will receive a complimentary Army Medical Department pen whether you decide to participate or not.

ALTERNATIVE TREATMENT
You do not have to participate in this study. In other words, your alternative to participating in this research study is *not* to participate in this study. You may cease participating in this study at any time.

CONFIDENTIALITY
Potentially identifiable information about you will consist of this consent form, surveys you complete and saliva samples you collect. However, all data will be maintained by the investigator and identities will be protected. Unidentifiable coding procedures will consist of your data record being assigned a subject code number by the study investigator. Identifying information will be removed from your data record and attached to the consent form and kept in a locked cabinet accessible only by the study investigators. A code sheet with the participant's name and code number will be kept in a separate locked file and will be accessible to the study investigators. All survey and laboratory data will be coded. In addition, study results will be aggregated such that no one will be identifiable in the final study results. Although results of this research may be presented at meetings or in publications, identifiable personal information pertaining to participants will not be disclosed. Data is being collected only for research purposes. None of your existing health or demographic information will be used in this study. When the study is completed, all of your data records will be destroyed. Access to all data will be limited to study personnel and a data and safety monitoring plan is established.

COMPENSATION FOR INJURY
Virginia Commonwealth University and the VCU Health System (formerly known as Medical College of Virginia Hospitals) have no plan for providing long-term care or compensation in the event that you suffer injury as a result of your participation in this research study.

If you are injured or if you become ill as a result of your participation in this study, contact your study doctor immediately. If you are currently on active duty in the military, it can be reasonably expected that any medical treatment you receive will be

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provided to you free of charge through the military health care system. Brooke Army Medical Center, your closest military health care system, is located on Fort Sam Houston in San Antonio, Texas at 3851 Roger Brooke Dr., Fort Sam Houston, TX 78234. The general information phone number there is 210) 916-4141; the Emergency Department's phone number there is (210) 513-9348. For outpatient appointments, the phone number is (210) 916-9900. The Tricare information phone number is (800) 444-5445.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide to not participate in this study. Your decision not to take part will involve no penalty or loss of benefits to which you are otherwise entitled. If you do participate, you may freely withdraw from the study at any time. Your decision to with draw will involve no penalty or loss of benefits to which you are otherwise entitled.

Your participation in this study may be stopped at any time due to administrative reasons requiring your withdrawal.

QUESTIONS

In the future, you may have questions about your study participation. You may also have questions about a possible side effect or any possible research-related injury. If you have any questions, complaints, or concerns about the research, contact the study investigator:

Laureen A. Otto
Cell phone: 804-386-4941
Email: gttols@vcu.edu

If you have questions about your rights as a research subject, you may contact:

Office of Research
Virginia Commonwealth University
800 East Leigh Street, Suite 113
PO Box 980568
Richmond, VA 23298
(804) 827-2157

You may also contact this number for general questions, concerns or complaints about the research. Please call this number if you cannot reach the research team or wish to talk to someone else.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions. Additional information about participation in research studies can be found at:
http://www.research.vcu.edu/irb/volunteers.htm

CONSENT

I have been provided with an opportunity to read this consent form carefully. All of the questions that I wish to raise concerning this study have been answered.

VL /NH/8-18-08
APPROVED

By signing this consent form, I have not waived any of the legal rights or benefits, to which I otherwise would be entitled. My signature indicates that I freely consent to participate in this research study. I will receive a copy of the consent form once I have agreed to participate.

_____
Subject Name, printed

_____ _____
Subject Signature Date

_____
Name of Person Conducting Informed Consent Discussion / Witness (Printed)

_____ _____
Signature of Person Conducting Informed Consent Discussion / Witness Date

VL / NH / 8-18-08
APPROVED

Vita

Laureen Annette Otto, PhD, RN
U.S. Citizen
Emails: ottola@vcu.edu
laureen.otto@us.army.mil

Education/Training

1982	BA	Luther College, Decorah, IA; Biology & Psychology
1987	ADN	Minneapolis Community College, Minneapolis, MN; Nursing
1994	BSN	Winona State University, Winona, MN; Nursing
2000	MS	University of Maryland, Baltimore, MD; Nursing & Health Policy
2009	PhD	Virginia Commonwealth University, Richmond, VA; Nursing

Positions and Employment

1987 – 1994	Nurse Case Manager and Consultant, (mental health and group home settings), Health Counseling Services, Minneapolis, MN
1994 – 1996	Clinical Charge Nurse, General Medicine (Volunteer Data Coder, Nursing Research Service), Walter Reed Army Medical Center, Washington, D.C.
1995 – 1996	Volunteer, Special Projects, Office of the Army Nurse Historian, U.S. Army Center of Military History, Washington, D.C.
1996 – 1998	Clinical Charge Nurse, Telemetry Unit, Veterans Administration Medical Center, San Antonio, TX
1996 – 1998	Nurse Officer, 5501st US Army Hospital, Cardio-thoracic ICU Staff Nurse, Brooke Army Medical Center, San Antonio, TX
1998 – 2000	Nurse Officer, 2290th US Army Hospital, Surgical ICU Staff Nurse, Walter Reed Army Medical Center, Washington, DC
2000 – 2000	Associate Researcher, Graduate Student Practicum (University of Maryland), Office of Science Policy & Public Liaison, Division of Extramural Activities, National Institute of Nursing Research (NINR), National Institutes of Health (NIH); Bethesda, MD
2000 – 2002	Nurse Officer, Troop Program Unit, Surgical ICU Staff Nurse, 348th General Hospital, Albany, NY
2000 – 2000	Nurse Workforce Data Analyst, Health Workforce Profile Group, Center for Health Workforce Studies, State University of New York, Rennselaer, NY
2000 – 2001	Doctoral Fellow, Nursing Research Assistant [for Chris Kovner, PhD RN FAAN], Nurse Workforce Research, College of Nursing, New York University, New York, NY

2001 – 2002	Associate Director, Practice and Governmental Affairs Program, Nursing Practice Issues and Health Policy Analysis, New York State Nurses Association, Latham, NY
2002 – 2003	IRR Nurse Officer (IRR), USAR Control Group (Reinforcement), USAR-HRC, St. Louis, MO
2002 – 2004	Nurse Research Assistant, Nurse Workforce Issues Research, New York State Nurses Association, Latham, NY
2002 – present	Member, Executive Board of Directors, Vietnam Women's Memorial Foundation, Washington, DC
2003 – 2006	Army Nurse Corps Historian (IMA), US Army Center of Military History, Ft. McNair, Washington, DC, with duty at Office of Medical History, US Army OTSG, Falls Church, VA
2004 – 2004	Chief, Staff Education Branch, Education Division, William Beaumont Army Medical Center, Fort Bliss, El Paso, TX (Activated Reservist)
2004 – 2005	Trauma Nurse Coordinator, Joint Theater Trauma Registry Team, 44th Medical Command; Green Zone/Baghdad and FOB Speicher/Tikrit, Iraq (Activated Reservist)
2005 – 2006	Associate Director, Practice and Governmental Affairs Program, Nursing Practice Issues and Health Policy Analysis, New York State Nurses Association, Latham, NY
2006 – present	Doctoral Candidate, LTHET, 32d Med Bde, AMEDD Student Detachment, Fort Sam Houston, TX, with duty at School of Nursing, Virginia Commonwealth University, Richmond, VA

Other Experience

1987 – present	Registered Nurse License, States of Minnesota
1987 – present	Public Health Nurse Certification, State of Minnesota
1999 – 2000	Maryland Senatorial Health Scholarship
2000 – 2001	New York University College of Nursing Doctoral Fellowship Scholarship
2002 – 2003	New York University College of Nursing Research Assistantship

Professional Memberships

Sigma Theta Tau International (Nursing Honor Society, since 1994), Gamma Omega Chapter, Virginia Commonwealth University
Phi Kappa Phi (National Academic Honor Society, since 2007), Virginia Commonwealth University
Southern Nursing Research Society
American Association for the History of Nursing
Association of Military Surgeons of the United States

Honors

1994	Army Service Ribbon

1994, 2004	National Defense Service Medal w/ Bronze Star Device
1996, 2004	Army Commendation Medal w/ one Oak Leaf Cluster
2000, 2001	Army Reserve Component Achievement Medal w/ one Oak Leaf Cluster
2004	Global War on Terrorism Service Ribbon
2004	Armed Forces Reserve Medal w/ Bronze Hourglass and "M" Device
2005	Army Meritorious Service Medal
2005	Iraq Campaign Medal
2006	Meritorious Unit Citation

Peer-Reviewed Publications

1. Otto, L. (1995). Healing after Vietnam: Diane Carlson Evans' story. *Journal of Emergency Nursing, 21*(5), 473-4.
2. Dill, M., Salsberg, E., Wing, P., Rizzo, A., Krohl, D., Fields, A., Moore, J., Tsao, H., Marzan, G., Myers, V., Acoma, C., Beaulieu, M., Szczepkowski, C., Forte, G., Dionne, M., Ayers, M., and Otto, L. (2000). *HRSA State Health Workforce Profiles*. Rockville, Maryland: Bureau of Health Professions, National Center for Health Workforce Information & Analysis, Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Services.
3. Otto, L. (2001). Nursing counts: Research brief – California's minimum nurse staffing legislation – what to expect. *American Journal of Nursing 101*(5), 62.
4. Otto, L. & Gurney, C. (2004). Ethnic diversity in the nurse workforce: A literature review. *Journal of the New York State Nurses Association, 37*(2), 16-21.
5. Otto, L. (2008). *Describing stress in military nurses*. Unpublished manuscript. Virginia Commonwealth University.
6. Otto, L. (2009). *Exploring the stress response in new Army nurses*. Unpublished manuscript. Virginia Commonwealth University.

Presentations/CE Publications/Teaching Experience

1. July 1999: Guest Lecturer, SPSS demonstration and survey research implications; Two-credit graduate level; "Working with Large Databases"; School of Nursing, Graduate School, University of Maryland at Baltimore.
2. October 2001: Continuing education online course, [www.nysna.org]; "Biological agent exposure: What every RN should know," New York State Nurses Association (2002), (2.4 contact hours).
3. May 2001 to June 2002: Lecturer, Nurse Malpractice Workshops/Nurse Delegation Workshops/Bioterrorism and Disaster Preparedness Workshops; Nursing Continuing Education, New York State Nurses Association.
4. March 2003: Paper Accepted for Panel Presentation; "Women at War: Wives, WACS, and Nurses During the Cold War"; 2003 Oral History Association Annual Conference; Bethesda, MD.
5. March 2005: Continuing education, "A History of the Army Nurse Corps," New York State Nurses Association (2005), (1.0 contact hour) .

6. September 2005: Continuing Education Presentation, “The Joint Theater Combat Trauma System,” New York State Nurses Association (2005), (1.0 contact hour).
7. February 2008: Poster presentation, “Stress in New Army Nurses,” Southern Nursing Research Society Annual Conference, University of Alabama at Birmingham.