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TITLE: Kaptur Combat Mental Health Initiative: Risk and Resilience Factors for
Combat Related Posttraumatic Psychopathology and Post Combat Adjustment

PRINCIPAL INVESTIGATOR: Joseph R. Calabrese, MD

CONTRACTING ORGANIZATION: University Hospitals of Cleveland
Cleveland, Ohio 44106

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14. ABSTRACT The general objective of the Ohio Army National Guard Mental Health Initiative is to support a series of projects that evaluate the relationships between resilience and risk factors, both cross-sectionally and longitudinally, before, during, and after deployment in the Ohio Army National Guard. The primary project collects long-term data on a random representative sample of up to 3,000 service members of the OANG, both treatment seeking and non-treatment seeking. Research visits are conducted at study entry and every 12 months for 10 years. Over the past year, five data analyses have been completed with three manuscripts currently under peer review, and six analyses in process. The investigators have focused analyses upon suicide and suicidal ideation, amongst others. Among veterans with war-related traumatic events, having PTSD was minimally associated with suicidal ideation, adjusting for history of mental illness and other covariates (AOR 0.943, 95% CI 0.253 – 3.52). In contrast, there was an adjusted association between PTSD status and suicidal ideation among veterans with civilian traumatic events (AOR 4.47, 95% CI 2.04 – 9.82), and association persisted when the analysis was limited to assaultive events only (AOR 15.1, 95% CI 3.14 – 72.3). This highlights that suicide rates in the army may not be linked to increased rates of PTSD from returning OIF and OEF veterans.					
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Ohio Army National Guard Mental Health Initiative

Risk and Resilience Factors for Combat-Related Posttraumatic Psychopathology and Post Combat Adjustment

Annual Report, October 2011

INTRODUCTION

Previously conducted research has demonstrated that deployment accompanied by combat experience results in increased risk of posttraumatic psychopathology and other mental health conditions. The general objective of the Ohio Army National Guard Mental Health Initiative is to create a research infrastructure capable of supporting a series of projects that evaluate the relationships between resilience and risk factors, both cross-sectionally and longitudinally, before, during, and after deployment. The primary project will collect long-term data on a random representative sample of up to 3,000 service members of the Ohio Army National Guard, both treatment seeking and non-treatment seeking. Research visits will be conducted at study entry and every 12 months for a minimum of 10 years. The Telephone Survey will be completed on all main project participants, and 500 of these participants will also have an in-depth In-Person Survey on an annual basis for the duration of the study. The Genetics Repository component collects a DNA saliva sample from consenting participants in the main project.

BODY

The Initiative is designed to study the relationships between 1) pre-existing mental illness/substance use disorders, 2) deployment to Operation Iraqi Freedom (OIF) or Operation Enduring Freedom (OEF), and 3) post-deployment related mental health and overall psychosocial adjustment and functioning. The study will evaluate several groups of the Ohio Army National Guard: those deployed to OIF (Iraq, Kuwait, or Qatar), those deployed OEF (Afghanistan), those deployed to other theaters (Bosnia, Turkey, Uzbekistan, Kosovo, on a ship, or other), those deployed domestically, and those not deployed.

Project #1 (main cohort – Telephone Survey and In-Person Survey) and Project #2 (Genetics component) are currently ongoing. An ancillary project entitled: “Neuroimaging and Genetic Investigation of Resilience and Vulnerability to PTSD” has been IRB approved and enrollment for this pilot project began in September 2011. A second ancillary project was submitted in October 2011 for R01 funding consideration at the National Institutes of Health and is entitled “Social environment and substance use: Using EMA to understand mechanisms”. Additional future ancillary projects are dependent upon outside funding being awarded, and may include a family study focusing on barriers to access to mental health care for service members, their families, and survivors.

Sites

The team of individuals and infrastructures committed to this project is extensive and has a reporting relationship to the leadership of the Ohio National Guard, The Ohio Adjutant General Deborah Ashenhurst and Assistant Adjutant General of the Army COL John Harris, through the Guard's OHIOCARES Workgroup. The Principal Investigator

(PI) of the Ohio Army National Guard Mental Health Initiative is Joseph R. Calabrese, M.D. and the Co-PI is Marijo Tamburrino, M.D. The Initiative includes a Coordinating Center based out of University Hospitals Case Medical Center (UHCMC) (Dr. Calabrese), and six operating research sites including University Hospitals Case Medical Center, the University of Toledo (Dr. Tamburrino), Columbia University Department of Epidemiology (Dr. Galea), a prestigious research survey firm, Abt SRBI, Inc. with a very long history of military research, the Ann Arbor VAMC Department of Psychiatry at the University of Michigan (Dr. Liberzon), and Michigan State University's Biomedical Research and Informatics Center - BRIC (Dr. Reed).

With Dr. Calabrese as the coordinating principal investigator, the UHCMC Coordinating Center is responsible for all aspects of project coordination (scientific, administrative, and fiscal) and the conduct of in-person assessments of 300 service members in their local communities. With Dr. Tamburrino as project Co-PI, the University of Toledo provides leadership and also conducts in-person assessments of 200 service members in their local communities. The Columbia University Department of Epidemiology responsibilities include, but are not be limited to, the design of the project's field procedures, including the annual Telephone Survey and In-Person Survey, scientific manuscript preparation, NIMH grant application, etc. Dr. Galea also serves as the primary interface between the project and the survey firm, Abt SRBI, which carries out the telephone surveys. The University of Michigan Ann Arbor VA Department of Psychiatry is responsible for the design, implementation, and oversight of the Genetics Repository, including laboratory and field procedures for biological sample collection, processing, storage, association analyses, etc. The Michigan State University Biomedical Research Informatics Center will provide all aspects of informatics needs for the In-Person Survey assessments, including data entry and management privileges, enrollment privileges, survey building privileges, etc.

Project #1

The primary study (Project #1) within this Initiative is a clinical epidemiology and health services project and is designed to function as the template upon which other projects, including but not limited to those of a translational research nature, will be superimposed. The first three specific aims of the primary research project were designed to build support and stimulate additional interest in the study of the role of resilience and risk in combat-related posttraumatic psychopathology and other similar adjustment problems.

Specific Aims of Project #1:

1. To study the relationship between deployment-related experiences and the development and trajectory of DSM-IV Axis I diagnoses
2. To document the factors across the life-course that are associated with resilience to DSM-IV Axis I diagnoses and with better post-deployment functioning
3. To study the relationship between National Guard-specific pre-deployment and post-deployment factors and the risk of development of DSM-IV Axis I disorders

Project #1 will interview up to 3,000 members of the Ohio National Guard, who were selected at random from the entire population of the Guard. All individuals who participate are interviewed for 1 hour by telephone on an annual basis, and began in November 2008.

A sub-sample of 500 participants of the telephone survey group is also interviewed on an annual basis and in-person, which on average last 2-3 hours. This sub-sample allows both for validation of key domains employed in the phone interviews and for further in-depth study of trajectory of psychopathology in this sample. Study personnel recommend that participants bring a family member, friend, or significant other for support and assistance during the interview. Family support often facilitates participant retention throughout the life of the project.

Research visits are conducted at study entry and every 12 months for a minimum of 10 years for both the telephone survey and in person survey. Currently, Year 3 of data collection is proceeding with the Telephone Survey sample. The participants have variable lengths of involvement and variable combat exposures, allowing us to suitably address the specific aims.

As recommended by the Scientific Advisory Board during the 2010 annual meeting, the investigators started a Dynamic Cohort with the start of Year 3 after receiving appropriate regulatory approvals. The investigators will sample new soldiers in the Guard on an annual basis with the intention of replenishing the sample in both the Telephone Survey and the In-Person Survey for participants who are unable to complete the annual survey for reasons including being currently deployed, lost to follow-up, etc.

Research Accomplishments from the Statement of Work for Project #1:

Tasks #1 - #5 from the Statement of Work delineate the critical events that must be accomplished in order for the project to be successful in terms of cost, schedule, and performance. Task #1 has been completed, with Tasks #2 through #5 currently in progress.

Task #1 – Baseline enrollment of up to 3,000 Ohio National Guard Members in the Telephone Survey, and 500 for the validation In-Person Survey, in order to be able to test Specific Aims #1 -3 with associated hypotheses. Enrollment for the Telephone Survey began 11/18/2008 after the recruitment period. Enrollment for the In-Person Survey began 12/10/2008. Baseline enrollment into both samples was completed on 11/17/2009 and 12/9/2009 respectively. The Telephone Survey enrolled N=2616, and the In-Person Survey enrolled N=500.

Task #2 – Annual participant follow-up to test Specific Aims #1 -3 with associated hypotheses. Year 3 interviews promptly began after Year 2 ended in late 2010 and are currently ongoing. As of 9/27/2011, the Telephone Survey has been completed with N=1818 participants (Year 3 follow up survey: N=1247; Dynamic Cohort Baseline Survey: N=572), and N=396 for the In-Person Survey (Year 3 follow up survey: N=311; Dynamic Cohort Baseline Survey: N=85).

Task #3 – Performance of a descriptive analysis of the data collected from the primary and sub-sample group including the prevalence of current mental illness and voluntary triage to OhioCares. At least one peer-reviewed publication per year will be derived from the study data.

We have performed several analyses of the data collected from the baseline sample and Year 2 sample of participants. For baseline analyses, we examined the broad range of characteristics that are hypothesized to be associated with mental health conditions, as well as potential mediators of these associations. As analyses were completed over the

past year, we presented the results at scientific conferences and submitted manuscripts for peer-reviewed publication.

The following manuscript has been published:

PTSD Comorbidity and Suicidal Ideation Associated with PTSD within the Ohio Army National Guard –Journal of Clinical Psychiatry. Please see **Appendix A** for the full text.

The following manuscripts have been submitted to peer-reviewed journals and are currently under review:

- The Ohio Army National Guard Mental Health Initiative: Data Collection, Sampling Validation and Baseline Results – submitted to the International Journal of Methods in Psychiatric Research
- Post-traumatic stress disorder and depression predict coincident alcohol abuse during and after deployment among recently deployed Army National Guard soldiers – submitted to Addiction
- The factor structure of major depression symptoms: A test of four competing models using the Patient Health Questionnaire-9 – submitted to Psychiatry Research
- Pre-, peri-, and post-deployment characteristics and the risk of posttraumatic stress disorder among Ohio National Guard soldiers – submitted to Annals of Epidemiology

The following analyses and manuscripts are in process and are entitled:

- PTSD symptom differences after war-related and civilian-related potentially traumatic events in military personnel
- Baseline prevalence of Axis I conditions in the in-person survey sample
- Incident alcohol disorder and mental health conditions
- Suicidal ideation after war-related and civilian-related potentially traumatic events in military personnel.
- Ethics in trauma research: participant reactions to trauma questions in the Ohio National Guard
- Cigarette smoking and suicidal ideation among military personnel: A prospective investigation.
- Alcohol abuse and dependence in the Ohio National Guard
- War and civilian PTSD and criterion A2
- Interface between childhood trauma, socioeconomic status, and comorbidities
- HIV risky behaviors in the Ohio National Guard
- Risky Behaviors in the Ohio National Guard sample
- Risky Behaviors and Suicidal Ideation
- Child Abuse and Depression
- Pre-, peri- and post-deployment factors and the incidence of alcohol abuse during or after deployment

The goal of these ongoing analyses is publication; the first six analyses have been completed, with the remaining currently in process.

PTSD symptom differences after war-related and civilian-related potentially traumatic events in military personnel

There is evidence that different types of potentially traumatic events can result in varying symptoms of PTSD. Given the differences between war- and civilian-related traumatic

events, it is possible that war-related and civilian-related PTSD may present with different symptoms. We used latent-class analysis to compare the pattern and distribution of the 17 PTSD symptoms to find similar groups (latent classes) of individuals with war-related and civilian-related potentially traumatic events. After identifying individuals with the highest score of symptoms from the latent class analysis, we compared the odds of each PTSD symptom between those with war vs. civilian related PTSD using multivariable logistic regression adjusting for gender, age, marital status, total experience of traumatic events and the time since the traumatic event. Those with war-related potentially traumatic events were more likely to have symptoms of physiologic reactivity (OR 5.59 95%CI 1.51-20.8), diminished interest in activities (OR 3.49, 95% CI 1.24-9.80) and feeling numb (OR 3.82, 95% CI 1.18 – 12.4). Future research should examine the implications of these increased symptoms among those with war-related events including possible link to more chronic conditions or co-morbidity.

Baseline prevalence of Axis I conditions in the in-person survey sample

One of the unique characteristics of the OHARNG MHI is the annual collection of data on all DSM-IV Axis I disorders. Using the Structured Clinical Interview for DSM-IV-TR, a full clinical diagnostic panel was administered to 500 randomly selected OHARNG soldiers. In this paper we outline the baseline prevalences of these conditions as well as how these prevalences differ by deployment status. The most common condition ever present was alcohol abuse (28.2%), followed by major depressive disorder (22.4%), alcohol dependence (20.4%) and drug use disorder (15.6%). Lifetime prevalence rates of mental health disorders were 66.4% and current prevalence rates were 24.4% in the OHARNG. The most prevalent lifetime disorders were alcohol abuse (28.2%), major depressive disorder (22.4%), and alcohol dependence (12.5%), while the most prevalent current disorders were generalized anxiety disorder (5.0%), major depressive disorder (4.8%) and alcohol abuse (3.4%). In addition, the most prevalent lifetime classes of disorders were substance use disorders (52.2%), mood disorders (30.0%), and anxiety disorders (19.6%), while for current prevalent classes of disorders were anxiety disorder (13.8%), mood disorders (7.6%), and substance use disorder (7.0%). In those who have never been deployed the highest lifetime prevalence was substance use disorders (44.2%) and for current disorders it was anxiety disorders (11.7%). Those who were deployed were more likely to have PTSD ($p < 0.01$) and alcohol abuse ($p < 0.01$). The longitudinal follow-up of this in-person cohort will provide a detailed measure of the trajectories of all Axis I conditions among National Guard soldiers. This information will be pivotal in understanding the needs of reserve forces during the reintegration period of the soldier from war to civilian life.

Incident alcohol disorder and mental health conditions

Alcohol use disorders are common in military personnel; however, it is not clear if mental health conditions increase the risk of during and post deployment alcohol abuse among this population. Ohio National Guards were randomly selected to complete computer assisted telephone interviews between June 2008 and February 2009. The primary outcome was reporting alcohol abuse meeting DSM-IV criteria first occurring during or post-deployment. Primary exposures of interest included during-/post-deployment major depressive disorder (MDD) and posttraumatic stress disorder (PTSD). Predictive logistic regression was used to determine the independent correlates of during-/post deployment alcohol abuse. Of 963 deployed participants, 113 (12%) screened positive for during-/post-deployment alcohol abuse, of whom 35 (34%) and 23 (33%) also reported during-/post-deployment MDD and PTSD, respectively. In a

multivariate model MDD (adjusted odds ratio [AOR] = 3.89, 95%CI: 2.12-7.15, $p < 0.001$) and PTSD (AOR=2.73, 95%CI: 1.37–5.42, $p = 0.004$) were associated with alcohol abuse. The conditional probability of during-/post-deployment alcohol abuse was 7%, 16%, 22%, and 43% among those with no MDD/PTSD, PTSD only, MDD only, and both PTSD and MDD, respectively. We observed a high prevalence of during-/post-deployment alcohol abuse among Ohio National Guards. Concurrent mental health conditions were highly predictive of developing alcohol abuse, and thus may constitute an etiologic pathway through which deployment-related exposures increase the risk of alcohol problems.

Suicidal ideation after war-related and civilian-related potentially traumatic events in military personnel.

There is recent evidence that the rate of suicide among Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF) are increasing compared to the general population. While it is well known that PTSD is a risk factor for suicidal outcomes (suicidal ideation, attempted suicide and completed suicide) little is known about how the event that leads to PTSD may then be associated with suicidal ideation. Specifically, it is unclear how war-related PTSD and civilian-related PTSD are associated with suicidal ideation. We used the baseline results from the telephone sample (N=2616) of the OHARNG MHI to compare the association between PTSD and suicidality for those with war-related traumatic events and those with civilian-related traumatic. Among veterans with war-related traumatic events, having PTSD was minimally associated with suicidal ideation, adjusting for history of mental illness and other covariates (AOR 0.943, 95% CI 0.253 – 3.52). In contrast, there was an adjusted association between PTSD status and suicidal ideation among veterans with civilian traumatic events (AOR 4.47, 95% CI 2.04 – 9.82), and association persisted when the analysis was limited to assaultive events only (AOR 15.1, 95% CI 3.14 – 72.3). This highlights that suicide rates in the army may not be linked to increased rates of PTSD from returning OIF and OEF veterans. Future studies should confirm these findings that it is civilian-related PTSD that linked to suicidal thoughts as compared to war-related PTSD.

Ethics in trauma research: participant reactions to trauma questions in the Ohio National Guard

Several studies have shown that participants in trauma research generally appreciate their research engagement and do not suffer inadvertent adverse effects (Griffin, Resick, Waldrop & Mechanic, 2003). However, this has not been examined in military populations. We evaluated the effects of asking Ohio National Guard (ONG) members to recall details of their trauma exposure, and to determine factors that may put participants at risk of becoming upset by such assessments. Of 500 participants, 17.2% (n=86) reported being upset during the survey and 7.0% (n=6) of those reported still being upset at the end of the session. The following diagnostic groups were more likely to report being upset by any of the survey questions: 36.2% of those with a history of childhood physical abuse ($p < .0001$), 33.9% of those with a history of childhood physical neglect ($p = 0.0004$), 37.1% of those with a history of childhood emotional abuse ($p < .0001$), and 47.5% of those with a history of childhood sexual abuse ($p < .0001$); 34% of those with suicidal ideation ($p = .001$); 37.3% of those participants who were female gendered ($p < .0001$); 24.4% of those participants who had a male-gendered interviewer ($p = .0002$); 22.5% of those who were the same gender as their interviewer ($p = .0057$); 31.8% of those who had Major Depressive Disorder ($p < .0001$), 37.5% of those who had Generalized Anxiety Disorder ($p = .013$), 50.0% of those who had Bipolar Disorder

($p=.0023$), 21.2% of those who had an alcohol use disorder ($p=.0274$), 28.6% of those who had a drug use disorder ($p=.0045$), and 61.3% of those who had Posttraumatic Stress Disorder ($p<.0001$). Most research participants were not upset as a result of the survey. Of the few participants who were upset by interview questions, those with mental health disorders were most likely to report being upset during the course of the interview, with only a small percentage still upset by the end of the interview. We did not find statistically significant differences from the following factors: high level of interpersonal conflict (found in the Conflict Tactics Scale), activity-limiting physical or emotional pain, number of deployments (stateside and overseas), marital status, employment, and socioeconomic status. Further research should be conducted to determine how a participant's emotional state at the end of an interview affects his/her continued participation in the research project. Also, it should be determined how elapsed time from the trauma to the interview affects a participant's emotional reaction to recounting the details of his/her trauma.

HIV risky behaviors in the Ohio National Guard

The primary hypothesis of this analysis is that a history of PTSD will be independently associated with an increased risk of engagement in past year HIV risk behavior(s). We will also test the hypothesis that greater levels of PTSD symptom longevity and severity will be positively associated with engagement in past year HIV risk behavior(s) in a dose-dependent manner. The primary outcome of this analysis is reporting at least one HIV risk behavior in the past year. Risk behaviors assessed include intravenous drug use, treatment for a sexually transmitted infection, exchanging sex for money or drugs, and unprotected anal intercourse. Note: participants do not have to indicate which HIV risk behavior(s) she/he engaged in. The primary exposure of interest is any posttraumatic stress disorder (PTSD) in one's lifetime. In secondary analyses, we will also examine the relationships between severity/longevity of PTSD symptoms and past year HIV risk behavior. For participants who report deployment and non-deployment related traumatic events, we will only consider symptoms pertaining to the most recent of these two types of traumatic events. The following variables will be included as possible confounders in block regression models: age, sex, race, income, education, marital status, history of fighting between caregivers, any depressive disorder (ever in lifetime), and screening positive for alcohol abuse (ever in lifetime).

Risky behaviors in the Ohio National Guard Sample

The goal of our analysis was to estimate the prevalence and correlates of risk-taking behavior among men and women in the Ohio Army National Guard (OANG). In particular, we were interested in exploring the extent to which mental health factors and combat-related exposures (deployment, traumatic events) predicted risk-taking and the extent to which psychosocial support variables were associated with decreased risky behavior. By studying both driving-related risky behaviors and HIV-related risk-taking, we sought to explore whether there were factors that increased risky driving, general risk taking, or both.

Risky behaviors and suicidal ideation

To describe and quantify the influence of Alcohol Use Disorders (AUDs; including both Abuse and Dependence) and risky health behavior on suicidal ideation and attempts. We hypothesize that those with AUDs are more likely to have had suicidal ideation or to have made a suicide attempt, compared to those who do not have any AUDs. Primary outcomes are suicidal ideation and suicide risk. The primary exposures of interest are DSM IV alcohol use disorder and risky health behaviors (including driving and HIV-risk

behaviors). We will examine DSM IV MDD and PTSD as potential confounders. Additionally, we will take into account and control for sociodemographic factors such as age, sex, race, and marital status.

Child abuse and depression

Applying a life course approach to depression, we wish to explore whether childhood experiences are a determinant of depression in adulthood. The main hypothesis is that individuals with negative childhood experiences (e.g. childhood physical and/or sexual abuse, neglect) are at greater risk for adult depression than individuals with positive childhood experiences (e.g. dependable social supports, experience of care and love) after adjustment for potential confounders. The primary outcome of this analysis is reporting on depression at T1 and/or T2, based on the DSM-IV criteria for Depression NOS. The primary exposures of interest are childhood experiences. We will also examine as possible confounders sex, age, race, income, employment, marital status, children at home, lifetime trauma history, current health status, branch of current and previous service, deployment history, future deployment expectations, and post-deployment supports.

Pre-, peri- and post-deployment factors and the incidence of alcohol abuse during or after deployment

We wish to determine whether pre-, peri- and post deployment support are associated with an alcohol disorder first occurring during/following deployment. The main hypothesis is that low deployment support groups will have a higher incidence of post-deployment alcohol disorder compared to higher deployment support groups, after adjustment for potential confounders. The primary outcome of this analysis is reporting an alcohol disorder during or following deployment, based on the DSM-IV criteria for alcohol dependence or abuse. The primary exposures of interest are pre-deployment preparation, unit support during deployment and post-deployment support. Other primary exposures may be major depressive disorder, PTSD, GAD, and most recent deployment location. We will also examine as possible confounders sex, age, race, income, education, marital status, and family history of drug and alcohol abuse.

Other

Please also see **Appendix B** for the Continuing Review Report with the annual update for the local IRBs, submitted in October 2011.

Task #4 – Annual oversight meetings for the Initiative.

The *Administrative Advisory Board (AAB)*, consisting of state and local leaders, administrators, and stakeholders providing guidance on non-scientific issues, is held on an annual basis. The most recent meeting was held on May 25, 2011 at Beightler Armory in Columbus, Ohio with representatives from the following:

- Leadership of OANG including TAG MG Ashenhurst and brigade commanders
- Ohio Dept of Mental Health
- Ohio Dept of Veterans Services
- Ohio Dept of Alcohol & Drug Addiction Services
- Ohio Assoc of County Behavioral Health Authorities
- Veteran's Affairs
- Columbus Veteran Center

From the data presented at the AAB the study team's aim was to present an overview of the data and to focus on clinical topics of areas of unmet need that the Guard may wish to study in depth. The study team is moving beyond dissemination into translation by engaging the brigade commanders in meaningful problem-solving, including an in-depth discussion revolving around the issue of completed suicides and suicide prevention. The study team added further questions to the annual survey in Year 4, slated to begin November 9, 2011, to assess the Guard's other interventions and programs, in order to continue to provide meaningful feedback.

The *External Scientific Advisory Board*, consisting of nationally and internationally renowned individuals with strong scientific backgrounds providing critical feedback on the scientific merit of the project, will also be held on an annual basis. The most recent meeting was held on May 24, 2011. The primary recommendations resulting from the recent SAB meeting were further analyses of the existing data, as well as several items of "hot-topic" interest to add to the Year 4 surveys. The manuscripts under peer review will also be circulated to the SAB members for feedback.

Task # 5 – Financial Reporting is due quarterly via SF425, and has been submitted regularly and on schedule over the past year. The most recent report was submitted on October 25, 2011 for the second quarter 2011. Additionally, the most recent Quarterly Report was submitted to TATRC and USAMRAA on October 25, 2011 for the first quarter 2011.

Project #2

The Genetics Repository component (Project #2) is a study on genetic determinants of risk and resilience to the development of PTSD and other mental illnesses. This first translational project involves the creation of a repository of saliva DNA samples, which will be used to perform genetic association studies on selected candidate alleles and potentially genome-wide analyses at multiple levels. These may include cross-sectional genetic association analyses of pre-deployment traits, longitudinal analyses to investigate genetic markers and functional polymorphisms involved in vulnerability to deployment-related psychiatric disorders (i.e. in case-control association analyses), as well as building models incorporating measures of deployment-related and pre-deployment environmental factors for vulnerability (i.e. gene x environment interactions). This will also allow for integrated research utilizing neuroimaging, psychophysiological, and neuroendocrine measures to investigate the effects of genetic variants on cognitive, behavioral, and physiological function at baseline and after deployment stressors.

Research Accomplishments from the Statement of Work for Project #2:

Task #1 – In order to test the 2 hypotheses in the Genetics Protocol, the participants in the Telephone Survey of Project #1 will be approached to participate in the Genetics Repository and will be asked to submit a saliva sample via a kit mailed to them. Final regulatory approval was granted 3/16/2010 by the DoD Office of Research Protections. Recruitment began on May 3, 2010 and will continue until all main study participants have been approached. As of September 27, 2011, 77% of participants have agreed to receive the Genetics kit in the mail after their Telephone Survey (N=1726 out of 2230) and 53% have returned their saliva sample, self report questionnaire, and consent form (N=921 out of 1726).

Task #2 – Upon receipt of saliva samples, the lab at the Ann Arbor VA processes them appropriately to provide genomic DNA preparation of the samples. Beginning in September 2011, Dr Liberzon made an internal arrangement to begin processing the samples for genotyping and preliminary analyses will be forthcoming over the next year.

Key Research Accomplishments

1. Completion of Year 1 (beginning November 2008) of data collection
 - Telephone Survey N=2616
 - In-Person Survey N=500
2. Year 2 data collection (beginning November 2009).
 - Telephone Survey N= 1770
 - In-Person Survey N=418 interviews completed (end date December 31, 2010 per the approved protocol window)
3. Year 3 data collection proceeding (beginning November 2010) as of September 27, 2011:
 - Telephone Survey N=1819 interviews completed thus far
 - o Year 3 follow up interviews: N=1247
 - o Dynamic Cohort baseline interviews: N=572
 - In-Person Survey N=396 interviews completed thus far
 - o Year 3 follow up interviews: N=311
 - o Dynamic Cohort baseline interviews: N=85
4. Genetics Repository data collection (beginning May 2010) as of September 27, 2011:
 - Agreed to receive Genetics kit: N=1726 out of 2230 (77%)
 - Returned completed Genetics kit: N=921 out of 1726 (53%)
5. Scientific Advisory Board Meeting on May 24, 2011
6. Administrative Advisory Board Meeting on May 25, 2011
7. One manuscript published over the past year, and four other manuscripts submitted to peer-reviewed journals over past year
8. Disseminated data through 5 professional meetings (ISTSS, SER, APA, All Ohio and NASW)

Reportable Outcomes

Presentations of study data:

1. Oral presentations:
 - a. Symposia presentation at the International Society for Traumatic Stress Studies 26th Annual Conference in November 2010, Montreal, Canada. Symposia composed of the following topics:
 - Ohio National Guard Mental Health Initiative. Galea S.
 - The Ohio National Guard Mental Health Initiative: baseline collection of a ten-year longitudinal cohort. Tamburrino M.
 - PTSD Comorbidity and Suicidal Ideation Associated with PTSD within the Ohio Army National Guard. Calabrese J.
 - PTSD Symptoms after war- and civilian-related traumas. Prescott M.
 - A “lifecourse” perspective on pre-, peri-, and post-deployment characteristics associated with the risk of posttraumatic stress disorder among Ohio Army National Guard soldiers. Galea S.
 - b. PTSD Comorbidity and Suicidal Ideation Associated With PTSD within the Ohio Army National Guard. Calabrese, J. American Psychiatric Association Annual Conference in May 2011.

- c. Content Expert on Resilience and provided an overview of the study results from the Ohio Army National Guard Mental Health Initiative. Tamburrino, M. Air Force Research Laboratory Resilience Workshop, September 2011.
- 2. Poster presentations:
 - a. Risky driving behavior among Ohio Army National Guard soldiers. Hoggatt K. Society for Epidemiologic Research in June 2011.
 - b. Ethics in trauma research: participant reactions to trauma questions in the Ohio National Guard. Wilson K. National Association of Social Workers Ohio Chapter Annual Conference October 2010, Columbus Ohio. Winner of first place award.
 - c. Baseline Results and Validation Methods of a 10 year Longitudinal Study of the Ohio Army National Guard. Tamburrino M. All Ohio Institute of Community Psychiatry Annual Conference on March 25-26, 2011, Cleveland Ohio.
 - d. Baseline Results and Validation Methods of a 10 year Longitudinal Study of the Ohio Army National Guard. Tamburrino M. American Psychiatric Association Annual Conference in May 2011.

*Abstracts (see **Appendix C** for reprints):*

- 1) National Association of Social Workers Ohio Chapter Annual Conference in October 2010:
 - Ethics in trauma research: participant reactions to trauma questions in the Ohio National Guard. Wilson K.
- 2) All Ohio Institute on Community Psychiatry in March 2011:
 - Baseline Results and Validation Methods of a 10 year Longitudinal Study of the Ohio Army National Guard. Tamburrino M.
- 3) American Psychiatric Association Annual Conference in May 2011:
 - Psychiatric Comorbidity in the Baseline Sample of 2,616 Soldiers in the Ohio Army National Guard Study of Combat Mental Health. Calabrese J.
 - Baseline Results and Validation Methods of a 10 year Longitudinal Study of the Ohio Army National Guard. Tamburrino M.
- 4) Joint Epidemiology Conference, Summer 2011:
 - Risky driving behavior among Ohio Army National Guard soldiers. Hoggatt K.
- 5) International Society for Traumatic Stress Studies 27th Annual Meeting in November 2011:
 - Mental health disorders increase the risk of during and post-deployment alcohol abuse among Ohio Army National Guards. Marshall B.
- 6) American College of Neuropsychopharmacology (ACNP) 50th Annual Meeting in December 2011. Panel Presentation: Identifying predictors of trauma response: State of the art of current prospective studies of PTSD:
 - Psychiatric Comorbidity in the Baseline Sample of 2,616 Soldiers in the Ohio Army National Guard Study of Combat Mental Health. Calabrese J.

*Published Journal Articles (please see **Appendix A** for reprint):*

- Calabrese, J. R., Prescott, M., Tamburrino, M., Liberzon, I., Slembariski, R., Goldmann, E., et al. (2011). PTSD comorbidity and suicidal ideation associated with PTSD within the ohio army national guard. *The Journal of Clinical Psychiatry*, 72(8), 1072-1078.

Manuscripts under Peer Review:

- 1) Goldmann E, Tamburrino M, Liberzon I, Prescott MR, Calabrese J, Slembariski R, Galea S. (2011). Pre-, peri-, and post-deployment characteristics and the risk of posttraumatic stress disorder among Ohio National Guard soldiers. *Annals of Psychiatry*, responses to reviewer comments and revisions submitted 9/28/2011
- 2) Tamburrino M, Prescott M, Calabrese J, Liberzon I, Slembariski R, Goldmann E, Shirley E, Fine T, Goto T, Wilson K, Ganocy S, Chan P, Derus A, Serrano M, Sizemore J, and Galea S. (2011). The Ohio Army National Guard Mental Health Initiative: Data Collection, Sampling, Validation and Baseline Results. *Journal of Methods in Psychiatric Research*, manuscript under review since 3/4/2011.
3. Marshall B, Prescott M, Calabrese J, Tamburrino M, Liberzon I, Slembariski R, Shirley E, Fine T, Goto T, Wilson K, Ganocy S, Chan P, Serrano M, Sizemore J, and Galea S. (2011). Post-traumatic stress disorder and depression predict coincident alcohol abuse during and after deployment among recently deployed Army National Guard soldiers. *Addiction*, manuscript under review since 8/2/2011
4. Elhai J, Contractor A, Tamburrino M, Fine T, Prescott M, Shirley E, Chan P, Slembariski R, Liberzon I, Galea S, and Calabrese J. (2011) The factor structure of major depression symptoms: A test of four competing models using the Patient Health Questionnaire-9. *Psychiatry Research*, manuscript under review since September 2011.

Miscellaneous:

1. Genetics Repository at Ann Arbor VA – accepting saliva DNA samples
2. Informatics – Michigan State University's RIX and OpenClinica database for the In-Person Survey, Abt SRBI, Inc.'s CATI database for the Telephone Survey

Supplementary Funding

Concerning our efforts to obtain additional funding for ancillary studies (as per the specific aims in the protocol) over the past year:

1. The University of Toledo and Ann Arbor VA sites (Tamburrino and Liberzon) have obtained internal institutional funding for a small pilot project entitled: *Neuroimaging and Genetic Investigation of Resilience and Vulnerability to PTSD*. The pilot study has obtained UT and VA IRB approvals. The investigators began recruitment in September 2011.
2. On October 5, 2011 the study investigators (Galea) submitted an R01 grant application to the Institutes of Health for the following proposed ancillary study: *Social environment and substance use: Using EMA to understand mechanisms*. If funded, earliest possible start date is July 2012.

Conclusion

This project will provide the military with novel, landmark long-term, prospective data that will elucidate novel predictors of resilience to combat-related stress. Compared to existing research in this area, this project is unique because it is population-based and does not limit its scope of study to only VA-treatment seeking veterans. Accordingly, this study is likely to uncover rates of PTSD and other mental conditions following combat that differ from those found in previous scientific reports.

Many previous projects have only utilized screening assessments, which can limit generalizability. The Telephone Survey, using a large representative sample,

incorporates many scales which go beyond screening in various domains. Additionally, the In-Person Survey methodology permits a more thorough, detailed prospective study of psychopathology and psychosocial factors, resulting in a wealth of data on this important military population.

The Ohio National Guard has expressed interest and commitment in having their programs assessed (i.e. suicide prevention and alcohol abuse awareness) via the annual surveys in order to adapt and improve their services and training programs. In conjunction with the Guard, the investigators incorporated these questions into the Year 4 surveys, slated to begin in November 2011.

This project also incorporates a genetics repository in conjunction with detailed, and prospectively longitudinal psychosocial data. The genetics component will allow us to study genetic determinants of risk and resilience to the development of PTSD and other mental illnesses.

References

Not applicable

PTSD Comorbidity and Suicidal Ideation Associated With PTSD Within the Ohio Army National Guard

Joseph R. Calabrese, MD; Marta Prescott, MPH; Marijo Tamburrino, MD;
Israel Liberzon, MD, PhD; Renee Slembariski, MBA; Emily Goldmann, MPH;
Edwin Shirley, PhD; Thomas Fine, MA; Toyomi Goto, MA; Kimberly Wilson, MSW;
Stephen Ganocy, PhD; Philip Chan, MS; Mary Beth Serrano, MA; James Sizemore, MDiv;
and Sandro Galea, MD, DrPH

Objective: To study the relation between posttraumatic stress disorder (PTSD) psychiatric comorbidity and suicidal ideation in a representative sample of Ohio Army National Guard soldiers.

Method: Using retrospective data collected on the telephone from a random sample of 2,616 National Guard soldiers who enrolled in a 10-year longitudinal study (baseline data collected November 2008–November 2009), we examined (1) the prevalence of other psychopathologies among those with DSM-IV–diagnosed PTSD compared to those without PTSD and (2) the association between PTSD comorbidity and suicidal ideation (reporting thoughts of being better off dead or hurting themselves). All analyses were carried out using logistic regression.

Results: Of guard members with PTSD in the last year, 61.7% had at least 1 other psychopathology; 20.2% had at least 2 other co-occurring conditions. The most common co-occurring psychopathology was depression. While those with PTSD overall were 5.4 (95% CI, 3.8–7.5) times more likely to report suicidality than those without PTSD, those who had at least 2 additional conditions along with PTSD were 7.5 (95% CI, 3.0–18.3) times more likely to report suicidal ideation at some point in their lifetime than those with PTSD alone.

Conclusions: Soldiers with PTSD were at increased risk for suicidality, and, among those with PTSD, those with at least 2 additional conditions were at the highest risk of suicidal ideation. Future research should address the mechanisms that contribute to multimorbidity in this population and the appropriate treatment methods for this high-risk group.

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Corresponding author: Joseph R. Calabrese, MD, 10524 Euclid Ave, Room 12-135, Cleveland, OH 44106 (joseph.calabrese@UHHospitals.org).

Community-based assessments of mental illness suggest that people with a lifetime history of posttraumatic stress disorder (PTSD) compared to those without are more likely to have another psychiatric condition and that few of those with PTSD have this condition alone.^{1–4} While the therapeutic challenges resulting from this degree of Axis I comorbidity indicate a need to further understand

PTSD comorbidity, recent work also suggests that this co-occurrence may be associated with suicidality.^{5,6}

In 2007, completed suicide was the second leading cause of death among those aged 25 to 34 years and the third most common cause among those aged 15 to 24 years in the United States.⁷ In military populations, the need to better understand the link between PTSD comorbidity and suicidality, one of the greatest predictors of suicide,⁸ is particularly acute given the high prevalence of PTSD comorbidity^{2,9} and high rates of suicide.^{10–12} However, there is no consensus on the interrelations among PTSD, PTSD comorbidity, and suicidal ideation in military populations. A recent study by Guerra and Calhoun⁹ examined Operation Enduring Freedom (OEF) and Operation Iraqi Freedom (OIF) veterans and found that while PTSD was associated with suicidality, the increase of comorbid conditions among those with PTSD was not associated with suicidality. In contrast, Jakupcak et al¹³ examined treatment-seeking OIF/OEF veterans and found that the risk of suicidality was higher among those with PTSD and at least 2 other psychiatric conditions compared to those with PTSD alone.

This lack of clarity suggests a need to understand the relation between PTSD, other psychiatric conditions, and suicidal ideation. In particular, work is needed to examine this relation in populations such as National Guard soldiers. Compared to their active-duty counterparts, reserve component soldiers often experience unique stressors that may negatively affect their mental health. For example, reserve forces are often deployed separately from their unit, maintain a civilian job while deployed, and have a time-limited amount of health care insurance after deployment.^{14–16} Additionally, since the first Gulf War, reserve forces have played an ever-increasing role in combat, contributing approximately 27% of combat forces in OIF/OEF as of 2007.¹⁷

This article uses the baseline data from a 10-year prospective cohort study of a random representative sample of the Ohio Army National Guard (OHARNG) to examine the prevalence of psychiatric comorbidity among those with PTSD and the relation between PTSD comorbidity and suicidal ideation.

METHOD

The National Guard Bureau and the institutional review boards of University Hospitals Case Medical

- When depression or alcohol dependence accompanies PTSD, view this clinical presentation as being accompanied by high risk for suicidality.
- Always look for co-occurring depression and alcohol dependence in PTSD.
- These 2 co-occurring illnesses increase the risk of suicidality more than 7-fold.

Center, University of Toledo, University of Michigan, Ann Arbor Veterans Administration Medical Center, Columbia University, and the Office of Human Research Protections of the US Army Medical Research and Materiel Command approved the study protocol. Verbal informed consent was obtained from all participants.

Study Population and Sampling

This study population was drawn from all serving members of the OHARNG between June 2008 and February 2009 who had addresses listed with the Guard (N = 12,225). After an alert letter was sent to all Guard members, 1,013 (8.3%) opted to not participate in the study. After eliminating those individuals who did not have a telephone number listed with the Guard (1,130; 10.1%) or incorrect numbers (3,568; 31.8%), we had 6,514 (58.1%) possible participants. Of these, 187 (2.8%) were not eligible (eg, too young or retired), 1,364 (20.9%) did not wish to participate, 31 (0.4%) were disqualified (eg, did not speak English), and 2,316 (35.6%) were not contacted before the cohort closed. Official enrollment (N = 2,616) and consent to participate in the study began in November 2008 and ended November 2009. Participants were compensated for their time.

Telephone Interview and Psychopathology Assessments

The computer-assisted telephone interview was field tested in November 2008. All assessments of psychopathology included questions to assess *Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition (DSM-IV) criteria. Additionally, questions on timing were included to assess whether or not the symptoms were present in the past 30 days, present in the past year, or ever present in the person's lifetime.

To assess self-perceived social support as well as collect information on traumatic events experienced during deployment, we used an adapted form of the Deployment Risk and Resilience Inventory.¹⁸ We used a modified form of the Life Events Checklist from the Clinician-Administered PTSD Scale^{19,20} to collect the frequency of traumatic events throughout their lifetime. The scale was modified to include additional questions used in other population-based studies to allow for comparisons.²¹

To assess PTSD, we used the PTSD Checklist-Civilian Version.²² PTSD symptoms were asked in relation to 2 traumas: the self-identified "worst" traumatic event from outside the person's most recent deployment and the self-identified

"worst" traumatic event experienced during their most recent deployment.^{19,20,23} To be diagnosed with PTSD, a person had to experience criteria A1 and A2 (experiencing a traumatic event and intense fear, hopelessness, and horror due to a trauma) as well as meet criterion B (at least 1 symptom of reexperiencing the trauma), criterion C (at least 3 symptoms of avoidance of the trauma), criterion D (at least 2 symptoms of hyperarousal), criterion E (duration of 1 month), and criterion F (significant impairment).²⁴ To have PTSD, a person had to meet all DSM-IV criteria related to a specific traumatic event and then have PTSD either from the traumatic event that occurred during their most recent deployment or from an event outside their most recent deployment.

We used the Patient Health Questionnaire-9 (PHQ-9)²⁵ to assess any depressive disorder. To be diagnosed with depressive disorder (including major depressive disorder [MDD]), a person had to have at least 2 or more co-occurring symptoms on the PHQ-9, with at least 1 being depressed mood or anhedonia.^{25,26}

To assess generalized anxiety disorder (GAD), we used the GAD-7.²⁷ To be diagnosed with GAD, a person had to have co-occurring symptoms with a score greater than or equal to 10, have symptoms for at least 6 months, and report functional impairment.²⁷

The Mini-International Neuropsychiatric Interview²⁸ was used to assess alcohol dependence and alcohol abuse. A lifetime history of alcohol abuse occurred if the individual met criterion A (at least 1 symptom of maladaptive pattern of substance use leading to impairment or distress) and criterion B (never met the classification for alcohol dependence).²⁸ A lifetime history of alcohol dependence was present if the individual met at least 3 symptoms of maladaptive pattern of substance abuse leading to impairment or distress.²⁸

To have suicidal ideation in their lifetime, individuals had to report feeling that they had ever had thoughts of being better off dead or wanting to hurt themselves as determined from the PHQ-9.^{25,26}

Clinical Interview

All psychopathology assessments were tested against a clinical reappraisal undertaken on a subsample of the study population (N = 500), and we found the assessments reliable and valid in this population. Participants recruited for this subsample were interviewed again using the full Structured Clinical Interview for DSM-IV Axis I Disorders and were compensated for their time. In our clinical reappraisal, we found the assessments had high specificity (ranging from 0.80 for alcohol abuse and 0.98 for generalized anxiety disorder) and were unlikely to classify individuals with a condition when they did not actually have the condition. The reliability estimates were similarly as high, with the Cronbach α ranging from 0.57 for alcohol abuse to 0.95 for PTSD from the most recent deployment (M.T., unpublished data, March 2011).

Statistical Analyses

We first compared the distribution of characteristics (ie, gender, age, education) of our sample to the OHARNG

Table 1. Characteristics of the Ohio Army National Guard Study Participants^a

Characteristic	Total (N=2,616)		Ohio National Guard 2008 Profile (N=10,778)		P Value
	n	%	n	%	
Gender					.16
Male	2,228	85.2	9,293	86.2	
Female	388	14.8	1,485	13.8	
Age					<.01
17–24 y	878	33.6	4,043	37.5	
25–34 y	848	32.5	3,746	34.8	
35–44 y	634	24.3	2,143	19.9	
45+ y	250	9.6	846	7.8	
Race					<.01
White	2,295	87.8	9,512	88.3	
Black	195	7.5	1,083	10.0	
Other	123	4.7	183	1.7	
Income					
≤ \$60,000	1,498	59.1	...	...	
> \$60,000	1,038	40.9	...	...	
Education					
High school graduate/GED or less	727	27.8	...	...	
Some college or technical training	1,234	47.2	...	...	
College/graduate degree	655	25.0	...	...	
Marital status					<.01
Married	1,227	47.0	4,154	38.5	
Divorced/separated/widowed	252	9.6	657	6.1	
Never married	1,134	43.4	5,967	55.4	
Rank					<.01
Officer	342	13.1	1,028	9.5	
Enlisted, cadets, and civilian employees	2,273	86.9	9,750	90.5	
Most recent deployment location					
Never deployed	939	36.1	...	...	
Nonconflict area	872	33.5	...	...	
Conflict area	793	30.5	...	...	
No. of lifetime deployments					
0–1	1,756	67.4	...	...	
2–3	682	26.2	...	...	
4+	169	6.5	...	...	
Total no. of all traumatic events experienced					
0	141	5.4	...	...	
1–5	887	33.9	...	...	
6–11	831	31.8	...	...	
12+	757	28.9	...	...	

^aSome percentages will not add up to the total due to missing values. All tests were conducted using a 2-tailed χ^2 test.
Abbreviation: GED = general equivalency diploma.

using 2-tailed χ^2 tests. We also described the prevalence of individual psychopathologies (PTSD, any depressive disorder, GAD, alcohol abuse, and alcohol dependence) and the prevalence of no conditions, at least 1 condition, and the co-occurrence of any of the conditions in 3 time frames: in the past month, in the past year, and ever in the person's lifetime.

To answer our first question, we used logistic regressions to examine the association between PTSD and psychiatric comorbidity. We compared the prevalence of other conditions within the past year (co-occurring depression, GAD, alcohol abuse, alcohol dependence, no other diagnosis, 1 other diagnosis, 2 other diagnoses, then 3 other diagnoses) among those with PTSD and without PTSD. We then examined these comparisons separately for men and women.²⁹

Table 2. Prevalence of Disorders in the Ohio Army National Guard Sample^a

Condition	Past Month		Past Year		Ever in Lifetime	
	n	%	n	%	n	%
PTSD	136	5.2	188	7.2	249	9.5
Depressive disorder	167	6.4	365	14.0	560	21.4
Generalized anxiety disorder	45	1.7	53	2.0	75	2.9
Alcohol abuse	68	2.6	139	5.3	628	24.0
Alcohol dependence	91	3.5	183	7.0	615	23.5
No disorder	2,224	85.0	1,932	73.9	1,099	42.0
At least 1 condition	304	11.6	496	19.0	1,060	40.5
At least 2 conditions	88	3.4	188	7.2	457	17.5

^aOne hundred forty-one people (5.4%) never had a trauma and were coded as never having PTSD for these statistics; 14 people (0.5%) refused or did not answer the PTSD symptoms and were coded as missing. One hundred eighteen people (4.5%) reported never having drunk alcohol in their life and therefore were coded as not having the condition. The combinations of conditions include those who never had a trauma and therefore were not at risk for PTSD.

Abbreviation: PTSD = posttraumatic stress disorder.

To answer our main question, we used logistic regression to examine the relation between comorbid presentation of PTSD and suicidal ideation. We compared a lifetime history of suicidal ideation among those with and without PTSD. Then, separately among those with PTSD, we examined the association between comorbid PTSD in the past year and suicidal ideation. The mode of survey administration resulted in the lack of collection on current alcohol use for 6% of participants. To determine how this may have affected our results, we ran sensitivity analyses assuming that these individuals all had an alcohol use disorder, that none did, or that a random proportion had an alcohol use disorder.

RESULTS

The characteristics of the baseline survey are described in Table 1. Similar to the OHARNG, our sample was predominantly male (85.2%) and white (87.7%). Our sample is slightly older than the OHARNG, and approximately half are married. Sixty-four percent had deployment experience, with the majority having between 1 and 3 deployments. The past month, past year, and lifetime prevalence of mental disorders in the total baseline sample (N=2,616) is described in Table 2. The most common mental disorder in the past month and past year, respectively, was depression (6.4%, 14.0%), followed by PTSD (5.2%, 7.2%). The most common condition ever reported was alcohol abuse (24.0%) relative to alcohol dependence (23.5%), depression (21.4%), PTSD (9.5%), and GAD (2.9%). In the past month, past year, and lifetime, respectively, 85.0%, 73.9%, and 42.0% of the individuals had none of these disorders.

The 12-month psychiatric comorbidity in soldiers with and without PTSD and then separately for men and women is described in Table 3. In soldiers with PTSD, the most prevalent condition was depression (48.9%), followed by alcohol dependence (17.0%) and GAD (16.0%). Compared to those without PTSD, GAD was 21.6 times more likely to occur in those with PTSD, and depression was 7.6 times more likely. Whereas alcohol dependence was 3.1 times more

Table 3. Distribution of Mental Health Conditions Comparing Individuals With PTSD Within the Past Year to Those Who Did Not Have PTSD Within the Past Year

	PTSD (n = 188)		No PTSD (n = 2,414)		Odds Ratio	Confidence Interval	
	n	%	n	%		Upper	Lower
Overall (N = 2,602)							
Conditions							
Depressive disorder	92	48.9	269	11.1	7.6	5.6	10.4
Generalized anxiety disorder	30	16.0	21	0.9	21.6	12.1	38.7
Alcohol abuse	14	7.5	125	5.2	1.5	0.8	2.6
Alcohol dependence	32	17.0	149	6.2	3.1	2.1	4.7
Co-occurrence of other conditions							
No other disorder	72	38.3	1,922	79.6	0.2	0.1	0.2
One other condition	78	41.5	423	17.5	3.3	2.5	4.5
Two or more other conditions	38	20.2	69	2.9	8.6	5.61	13.2
Men (n = 2,215)							
	n = 145		n = 2,070				
Conditions							
Depressive disorder	67	46.2	216	10.4	7.4	5.2	10.5
Generalized anxiety disorder	27	18.6	16	0.8	29.4	15.4	56.0
Alcohol abuse	12	8.3	114	5.5	1.5	0.8	2.9
Alcohol dependence	29	20.0	139	6.7	3.5	2.2	5.4
Co-occurrence of other conditions							
No other disorder	56	38.6	1,647	79.6	0.2	0.1	0.2
One other condition	55	37.9	364	17.6	2.9	2.0	4.1
Two or more other conditions	34	23.5	59	2.9	10.4	6.6	16.6
Women (n = 387)							
	n = 43		n = 344				
Conditions							
Depressive disorder	25	58.1	53	15.4	7.6	3.9	14.9
Generalized anxiety disorder	3	7.0	5	1.5	5.1	1.2	22.1
Alcohol abuse	2	4.7	11	3.2	1.5	0.3	6.9
Alcohol dependence	3	7.0	10	2.9	2.5	0.7	9.5
Co-occurrence of other conditions							
No other disorder	16	37.2	275	79.9	0.1	0.1	0.3
One other condition	23	53.5	59	17.2	5.6	2.9	10.8
Two or more other conditions	4	9.3	10	2.9	3.5	1.03	11.4

Abbreviation: PTSD = posttraumatic stress disorder.

Table 4. Lifetime History of Suicidal Ideation Among Those With Current PTSD and Those With PTSD Accompanied by Psychiatric Comorbidity

	History of Suicidal Ideation		Odds Ratio	Confidence Interval	
	n	%		Lower	Upper
Association with current PTSD					
No PTSD (n = 2,410)	200	8.3	Reference	...	...
Current case of PTSD (n = 187)	61	32.6	5.4	3.8	7.5
Association with PTSD accompanied by comorbidity					
Current PTSD only (n = 72)	13	18.1	Reference	...	...
Current PTSD + 1 (n = 78)	25	32.1	2.1	1.0	4.6
Current PTSD + 2 or more (n = 37)	23	62.2	7.5	3.0	18.3

Abbreviation: PTSD = posttraumatic stress disorder.

likely, alcohol abuse was reported to the same extent in those with and without current PTSD. Those with PTSD were very unlikely to have no other lifetime disorder. When we stratified by gender, results were largely comparable, but we did find that while male soldiers with PTSD were 29.4 times more likely to have GAD compared to males who did not have PTSD, female soldiers were only 5.1 times more likely.

Table 4 and Figure 1 display the association between a lifetime history of suicidal ideation and PTSD as well as

comorbid PTSD. Those with PTSD (as compared to those without) were 5.4 times more likely to have a history of suicidal ideation. Soldiers with PTSD and at least 2 comorbid conditions had 7.5 times greater odds of reporting suicidal ideation compared to those with PTSD only.

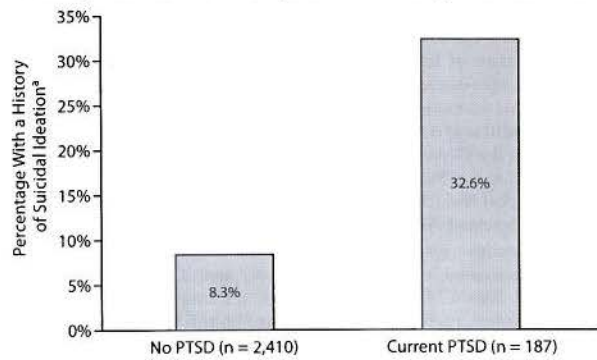
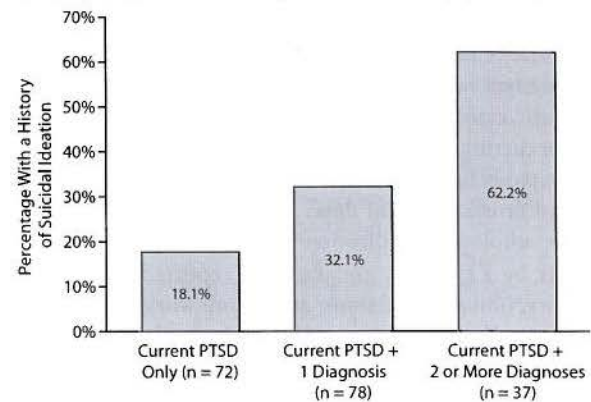
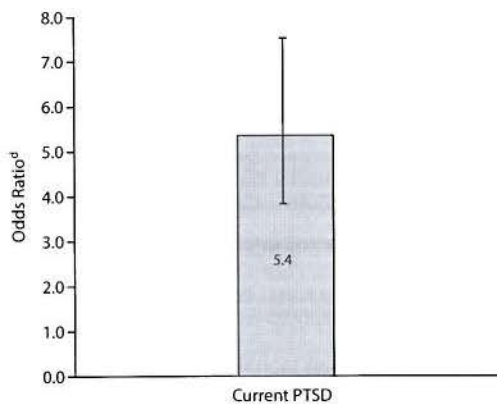
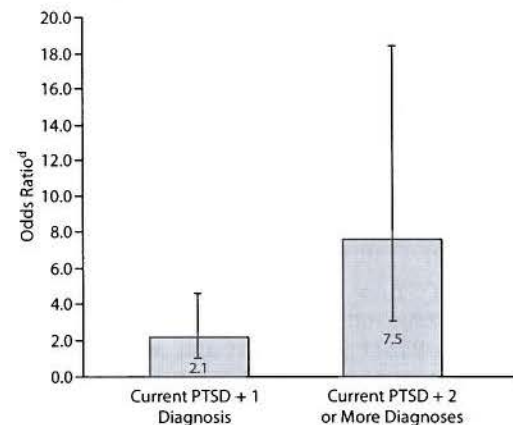
There were no statistically significant or meaningful differences in the associations reported here in the sensitivity analyses.

DISCUSSION

In a representative sample of OHARNG soldiers, we found that those with PTSD were more likely to report suicidal ideation. Among those with PTSD, comorbidity with more than 1 disorder was associated with a higher risk for suicidal ideation. The general association between PTSD and suicidal ideation in National Guard soldiers adds to the growing evidence for this association in military populations.^{9,13,30} With respect to PTSD comorbidity, we found a specific association: among those with PTSD, those with 2 or more comorbid disorders were 7 times more likely to have ever reported suicidal ideation as compared to those with PTSD only. These results were consistent with work by Jakupcak et al,¹³ who found that compared to veterans with PTSD alone, those with 2 or more additional conditions were more likely to report suicidal ideation.

Considering the prevalence of PTSD multimorbidity, the relation between PTSD with multiple disorders and suicidal ideation has particular clinical import. Within the past year, 61.7% of soldiers with PTSD had at least 1 other condition and 20.2% had at least 2 other conditions, a level comparable to other military populations.^{2,31} In comparison, 2 or more conditions were present in only 2.9% of those without PTSD. The prevalence of multiple conditions among those with PTSD and the increased association of this group with suicidal ideation highlight a singular subgroup of clinical and therapeutic concern.

We found that the most common co-occurring condition with PTSD was depression, at 48.9% (46.2% among men and 58.1% among women). While we used a definition of depression that was not limited to MDD alone, several studies that examined MDD found a similarly high prevalence among those with PTSD.^{1,32,33} In military populations, 56% of Israeli soldiers seeking PTSD treatment recently had major depressive disorder,³² and 52% of a population-based sample of Australian Korean War veterans who had PTSD recently had MDD.³³ The increased risk of depression among those with PTSD (7.6-fold over those without PTSD) was comparable to 2 population-based military studies including the Millennium Cohort (4-fold increase in men and 3-fold increase in women for MDD) and the National Vietnam Veterans Readjustment Survey (10-fold increase for MDE).^{2,34} The implications of this overlap have been reported in other studies, which found

Figure 1. Individuals With PTSD as Well as Those With PTSD Multimorbidity Were More Likely to Have a History of Suicidal Ideation^a**A. History of Suicidal Ideation by Current PTSD Diagnosis (model 1)^b****B. History of Suicidal Ideation by PTSD Comorbidity (model 2)^c****C. Odds of a History of Suicidal Ideation Given Current PTSD Diagnosis (model 1)****D. Odds of a History of Suicidal Ideation Given PTSD Comorbidity (model 2)**^aLifetime prevalence.^bModel 1 result: compared to 200 of those without PTSD (n = 2,410), 61 of those with PTSD (n = 187) had a history of suicidal ideation.^cModel 2 result: compared to the 13 of those with only PTSD (n = 72), 25 of those with PTSD and 1 more condition (n = 78) and 23 of those with PTSD and 2 or more other conditions (n = 37) had a history of suicidal ideation.^dLogistic regression. Bar represents confidence interval.

Abbreviation: PTSD = posttraumatic stress disorder.

higher severity of PTSD symptoms, poor self-reported quality of life, and increased functional impairment and suicidal ideation among those with PTSD and depression compared to those with either condition alone.^{3,33,34} Future research should focus on persons with co-occurring mood-anxiety disorders as a particularly vulnerable group.

In our sample, the second most prevalent condition among those with PTSD was alcohol dependence. Often reported along with alcohol abuse as the most common co-occurring condition with PTSD,³⁵ alcohol dependence had a high prevalence overall among those with PTSD (17.0%). This was primarily a concern among men with PTSD (20.0%). This prevalence of alcohol dependence was lower than that reported in the National Comorbidity Survey (men 52% and women 30%) but comparable to other military studies. Kulka et al² reported 22% of current alcohol abuse or dependence cases among those with PTSD in the National

Vietnam Veterans Readjustment Survey, and 39% of those with PTSD had some form of alcohol disorder (abuse or dependence) in the Vietnam Experiences Study.³ We found that, compared to those without PTSD, those with PTSD were 3.1 times more likely to have had alcohol dependence within the past year. In contrast to alcohol dependence, we found no increase in the prevalence of alcohol abuse among those with PTSD compared to the rest of the sample—alcohol abuse was reported to the same extent regardless of mental health or gender. Further research is necessary to examine the association between alcohol dependence and PTSD, as it may be a result of alcohol dependence preceding PTSD³ but also may be a result of self-medication to deal with the symptoms of PTSD.^{3,35,36} Regardless, the therapeutic concerns for this overlap are similar to those of other conditions and include diagnostic concerns³ as well as treatment implications.^{35–37}

Clinicians and family members should be alert to the clinical relevance of presentations of PTSD complicated by major depressive episodes and/or alcohol dependence. These 2 types of comorbidity appear to increase the risk of suicidality more than 7-fold. It may be useful for clinicians to meet with family members at the time of the initial diagnostic assessment to inquire about these specific types of co-occurring illnesses.

This study has several limitations. We utilized retrospective and cross-sectional data. While we cannot tell if the psychopathologies predisposed suicidal ideation, the meta-analysis by Kryszynska and Lester³⁰ reported evidence of both directional associations, and future work will examine the longitudinal aspects of PTSD and suicidal ideation. In addition, these psychopathologies are self-reported, which may lead to misdiagnosis given the retrospective and non-clinical nature of the data. Similar to the above limitation, longitudinal clinical data should be examined to see if these associations are robust. Regardless, in our validation testing using the clinical subsample, we found that the specificity of our assessment tools was high, and therefore those who were classified as probable cases were likely to have the condition in question. Moreover, we found no evidence of specificity differences by gender (except for alcohol abuse), race, or age for all mental health diagnoses (data available upon request) that argues that any misclassification would likely be non-differential, and therefore any associations are likely a conservative estimate. Due to the time limitation of the telephone survey, we were unable to collect more mental health conditions, and future work needs to examine the relation between PTSD comorbidity and suicidal ideation considering all Axis I and Axis II conditions. Given the robustness of sensitivity analysis, it is unlikely that the mode of survey administration had a substantial impact on absolute prevalences. However, it is possible that relative ranking of disorders with similar prevalences would be altered under different conditions.

The strengths of this work are due to the strong qualities of the OHARNG Mental Health Initiative. The study is a large, population-based sample of National Guard soldiers representative of OHARNG. Therefore, the conclusions may be generalizable to OHARNG and the Army National Guard.

CONCLUSION

In the OHARNG Mental Health Initiative, the majority of current persons with PTSD also had at least 1 other psychiatric condition; 20% had multiple conditions. PTSD multimorbidity was strongly associated with a history of suicidal ideation. Future work should examine all Axis I and Axis II conditions in relation to PTSD comorbidity and suicide risk. In addition, work should investigate the mechanisms linking PTSD with multiple conditions to suicidal ideation. Clinical implications include a need to monitor this high-risk group for indications of suicidal thoughts and examine effective methods of treatment for persons with PTSD multimorbidity.

Author affiliations: Department of Psychiatry, University Hospitals Case Medical Center, Case Western Reserve University, Cleveland, Ohio (Drs Calabrese, Shirley, and Ganocy; Mss Slembariski, Goto, and Serrano; and Mr Chan); University of Michigan, Ann Arbor, Michigan (Mss Prescott and Goldmann and Drs Liberzon and Galea); Columbia University, New York, New York (Mss Prescott and Goldmann and Dr Galea); University of Toledo Health Science Center, Toledo, Ohio (Dr Tamburrino, Mr Fine, and Ms Wilson); and Ohio Army National Guard, Columbus (Mr Sizemore).

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CONTINUING REVIEW ABSTRACT & STATUS REPORT

TITLE: Ohio Army National Guard Mental Health Initiative (ONARNG MHI): Risk and Resilience Factors for Combat-Related Posttraumatic Psychopathology and Post Combat Adjustment

IRB#: 03-06-46

ABSTRACT

SUMMARY OF PURPOSE, AIMS, & OBJECTIVES:

Since 2005 a team of investigators have been working with Congresswoman Marcy Kaptur and the Department of Defense on operationalizing the Ohio Army National Guard Mental Health Initiative (ONARNG MHI). The general objective of this effort is to evaluate the relationships between risk and resilience factors, both cross-sectionally and longitudinally, before, during, and after deployment.

The primary research project for this initiative was garnered through a 2006 Department of Defense congressional special interest award and is entitled "Risk and Resilience Factors for Combat-Related Posttraumatic Psychopathology and Post Combat Adjustment". The protocol and study documents were reviewed by the U.S. Army Medical Research and Materiel Command (USAMRMC), Office of Research Protections (ORP), Human Research Protection Office (HRPO) and found to comply with applicable DOD, U.S. Army, and USAMRMC human subjects protection requirements on October 1, 2008.

The Coordinating Principal Investigator for the project is Joseph R. Calabrese, MD, and the Co-Principal Investigator, Marijo Tamburrino, MD (University of Toledo). Field Procedures are directed by Sandro Galea, MD, Dr.PH, Professor of Epidemiology and Chairman, Mailman School of Public Health, Columbia University. Responsible for the development of future Translational Research projects will be Israel Liberzon, MD, PhD, Professor of Psychiatry & Neuroscience, Ann Arbor VA. The Coordinating Center is based out of University Hospitals Case Medical Center at Case Western Reserve University. The survey firm, Abt SRBI, Inc., carries out telephone interviews and investigators at University Hospitals Case Medical Center and the University of Toledo carry out in-person research assessments. The data is stored at Abt SRBI, Inc. for the Telephone Survey and psychosocial data associated with the Genetics Study. The In-Person Survey data is stored at Michigan State University's Biomedical Research Informatics Core headed by Philip Reed, PhD. DNA saliva samples are stored at the Ann Arbor VA.

This initiative is overseen by the Ohio National Guard, the Office of Congresswoman Marcy Kaptur, the Department of Defense's Military Operational Medicine Research Program (MOMRP) and the Telemedicine & Advanced Technologies Research Center (TATRC) (last annual Product Line Review Meeting on April 27, 2010), the Initiative's External Scientific Advisory Board (last annual meeting May 24, 2011) and External Administrative Advisory Board (last annual meeting May 25, 2011).

The primary study within this initiative is a clinical epidemiology and health services project and is designed to function as the template, upon which other projects, including but not limited to those of a translational research nature, will be added. Accordingly, this project has obtained permission to re-contact previously studied, well-characterized research subjects and their family members for future research that specifically targets the

improvement of the scientific understanding of combat-related posttraumatic psychopathology and similar adjustment problems.

METHODOLOGY:

This project is designed to interview a representative sample of up to 3,000 members of the Ohio National Guard on an annual basis for 10 years, which started in November 2008. These Guard members participate in the primary sample and complete an interview over the telephone. Group assignment to the telephone interview is made randomly from the entire population of the Ohio National Guard (~12,000) on an ongoing basis with the dynamic cohort sampling each year of new members of the Ohio National Guard. Research visits are conducted at baseline and also every 12 months for 10 years through the end of 2018. In addition, 500 participants, randomly selected from the telephone sample, complete annual in-person interviews as a part of a validation sub-sample. We have obtained a random representative sample of National Guard members that will have variable lengths of involvement and combat exposures, allowing us to adequately address the proposed aims.

The Telephone Survey requires 60 minutes on average (depending on the individual history of the service member) and constitutes the primary dataset, whereas the In-Person Survey requires 2-3 hours (depending on individual history). The In-Person Survey is used to validate key domains employed in the telephone survey, gather more in-depth information and across different domains, and to further study of the longitudinal trajectory of PTSD. The Genetics Repository began in May 2010 and all cohort participants from the main study are being approached to provide informed consent, complete a self-report survey, and provide a saliva sample from which DNA will be extracted.

STATUS REPORT

Summary

Over the past year, the OHARNG MIH has been collecting data for Year 3 of the main project. Year 3 began on November 10, 2010 for the Telephone Survey and December 13, 2010 for the In-Person Survey. As per the protocol, the Year 4 Surveys and the new Dynamic-Cohort Baseline Surveys will begin with pilot interviews to ensure protocol and consent-stated duration of interviews is met, tightening up questions in response to participant and interviewer feedback, correcting administrative errors such as skip patterns, etc. If changes are required to the In-Person Surveys (Year 4 and Dynamic Cohort Baseline) after the pilot periods starting November 9, 2011 for the Telephone Survey and December 12, 2011 for the In-Person Survey, the investigators will submit the revised surveys to the IRB for approval.

Telephone Survey (interviewed by Abt SRBI, Inc):

Year 2 Interviews:

At the time of the last continuing review (January 12, 2010), there were 2,610 active participants from the original N=2,616. Year 2 enrollment closed on July 31, 2011. A summary of enrollment activity since the last CR is as follows (data reported as of October 17, 2011):

1. 1,770 participants out of the 2,610 have completed the Year 2 Telephone Survey,¹¹¹ since the last CR report (from January 12, 2010). The cooperation rate for the Telephone Survey was 93.4%. The participants who declined did not withdraw from the study but were not able to complete the Year 2 survey at the time they were contacted. They will be re-contacted in Year 3.

Year 3 Interviews:

At the time of the last continuing review (January 12, 2010), there were 217 active participants from the original N=2598. A summary of enrollment activity since the last CR is as follows: (Data reported on October 17, 2011)

1. As of October 17, 2011, N= 1, 273 Year 3 interviews have been completed thus far. The cooperation rate for Year 3 Telephone Survey is 88.5%. The participants who declined to participate did not withdraw from the study but were not able to complete the Year 3 survey at the time they were contacted. They will be re-contacted in Year 4.

Dynamic-Cohort Baseline Interviews:

At the time of the last continuing review (January 12, 210) there were 24 active participants in the Dynamic Cohort Baseline. A summary of enrollment activity since the last CR is as follows: (Data reported on October 17, 2011).

1. As of October 17, 2011, N=573 DC-B interviews have been completed thus far. The cooperation rate for the DC-B survey is 66.1%, which means that N=39 declined to participate.

Telephone Survey Withdrawals:

Since the beginning of the main telephone survey, a total of 33 participants have withdrawn from the study. 5 participants were withdrawn from the study due to death (not study-related) and 28 participants have withdrawn voluntarily.

Genetics Study (approached by Abt SRBI, Inc. interviewer at the end of the Telephone Survey):

Recruitment began on May 3, 2010. Since that time (data reported as of October 17, 2011):

1. N=2,240 participants have been approached on the Telephone Survey (Year 2, Year 3, and Dynamic Cohort Baseline).
2. N=1,732 participants have agreed to receive the Genetics Kit via mail (77% positive response)
3. N=928 completed kits (consent form, self report survey, and saliva DNA sample) have been returned (54% return rate).

In-Person Survey (interviewed by UHCMC and UT clinician interviewers):

Year 2 Interviews:

At the time of the last continuing review (November 29, 2010), there were 499 active participants from the original N=500. A summary of enrollment activity since the last CR is as follows (data reported as of December 21, 2010):

1. Year 2 Interviews Completed: N=418. UHCMC site N=229; UT site N=189
2. Scheduled but not yet completed: Year 2 Interviews: N=0.
3. Pending to be scheduled: N=0.
4. Delayed participants (could not complete the interview when initially contacted and asked to be contacted later, which is still pending): N=2
5. Year 2 Declined participants (will be contacted again in Year 3): N=3
6. Year 2 Lost to follow-up participants (were sent IRB approved non-contact letter and we will attempt to find them again in Year 3): N=54
7. Deployed participants (will be contacted for Year 3 upon their return): N=10

Year 3 and Dynamic Cohort Interviews:

At the time of the last continuing review (November 29, 2010), there were 494 active participants from the original N=500. A summary of enrollment activity since the last CR is as follows (data reported as of October 17, 2011):

1. Year 3 Interviews Completed: N=317. Dynamic Cohort Interviews Completed: N=91, Cumulative enrollment N=408, of which UHCMC site N=268; UT site N=140
2. Scheduled but not yet completed: N=64.
3. Pending to be scheduled: N=28.
4. Delayed participants (could not complete the interview when initially contacted and asked to be contacted later, which is still pending): N=7
5. Year 3 Declined participants (will be contacted again in Year 4): N=12
6. Year 3 Lost to follow-up participants (were sent IRB approved non-contact letter and we will attempt to find them again in Year 4): N=51
7. Deployed participants (will be contacted for Year 4 upon their return): N=40
8. Screen Failures N=74 for the following reasons:
 - a. Deployment
 - b. Unable to contact
 - c. Live out of state
 - d. Not interested in participating.

In-Person Survey Withdrawals:

Since the beginning of the In-Person Survey, a total of 15 participants have withdrawn from the study for the following reasons:

1. N=1 participant is deceased
2. N=12 withdrawn consent for the following reasons:
 - a. No longer interested in research: N=4
 - b. Interview upsetting: N=1
 - c. Too busy to participate: N=7
3. N=2 was withdrawn from the study for non-compliance

Electronic Data Capture in the In-Person Survey:

During Year 3, the majority of interviews were done in the electronic RIX system housed at Michigan State University, as described in the protocol. Some interviews had to be completed on paper due to technological problems, including internet connectivity lapses, particularly in rural areas of the state, basements of libraries, problems on MSU's end, etc. Any interviews completed on paper are double data-entered into the RIX database for reliability purposes.

As the informatics team recommended as their RIX system is aging and the internet connectivity problems persist, the study team has developed a solution with Michigan State University to transition into OpenClinica (OC), as approved in the protocol by the IRB since the last CR. Since obtaining IRB approval, the study team has developed the forms and tested the surveys thoroughly to ensure that the surveys are administered as IRB approved. A training day with the study team and MSU has been scheduled for October 27, 2011. This transition will begin with the Dynamic Cohort participants on October 31, 2011, and with the Year 4 follow up interviews on December 12, 2011. If needed, the emergency procedures remain to complete the interviews on paper, which will be double-data entered into the OC database.

As reported in the last CR, the full transition to RedCap survey, a web-based version of the Self-Report Survey, has taken place. As of October 17, 2011, 304 Year 3 participants have completed the self-report survey in RedCap. Any self-report surveys completed on paper, due to internet connectivity or participants request, are also double data entered into RIX for reliability purposes.

Year 4 and Dynamic Cohort Baseline

Interviewer training for the new surveys is scheduled for December 7-8, 2011, with the pilot periods starting December 12, 2011 and slated through January 31, 2012. After the pilot periods are over, any required changes to the In-Person Surveys will be submitted to the IRB.

Adult Relative Registry (approached by the In-Person team):

Recruitment into the Registry remains closed. When an ancillary family study is funded the investigators will inform the IRB and will re-open recruitment if needed.

EVENT REPORTING: ADVERSE EVENTS, UNANTICIPATED EVENTS, AND PROTOCOL DEVIATIONS

Serious Adverse Events

There has been 1 Serious Adverse Event since the last CR report from the University of Toledo for an In-Person Survey participant, #0080 on 1/20/2011. Please see attached SAE report with a synopsis and letter from the DSMB stating that the event was unrelated and unexpected.

1. Participant #0080 (external- UT site): serious, not study related, unexpected

Unanticipated Problems

There have been 5 unanticipated problems including 1 that was withdrawn, reported to the UHCMC IRB over the past year since the last CR report.

1. Reported to the IRB on January 11, 2011: After IRB approval in August 2010, the Dynamic Cohort study recruitment began in November 2010. As per the approved protocol, Abt SRBI, Inc, the Telephone Survey firm, received a list of potential participants from the Ohio National Guard who had not opted out after receiving the study alert letter in October 2010. They began making recruitment phone calls on November 17, 2010. After the Dynamic Cohort Baseline Survey was complete, the SRBI accounting department noticed that a few participants were already in their database as having been paid and so queried the project team as to whether another check should be issued. It was discovered that two respondents were mistakenly interviewed in the Dynamic Cohort survey before we discovered that there were duplicate cases in the new sample provided by the Guard. These 2 soldiers had been part of the original cohort and presumed we were calling to conduct their next annual survey (currently Year 3).
2. Reported to the IRB on February 9, 2011: Participant 0562 of the in-person survey had requested to be removed from the study on 8/27/2010 because he found the interviews to be upsetting. This was documented within the in-person component of our study, but was not communicated to the telephone interview component of the study. As a result, he was contacted at his anniversary date and a Year 3 phone interview was conducted with this participant on 1/21/2011. The participant re-consented over the phone as per the protocol and IRB approved Telephone Survey before the interview was conducted. However, he became upset during the course of the interview and per the safety measures built into the study asked if he wanted to

speak with a clinician, requiring a phone triage assessment, where the study team learned of the continued contact with this participant. The In-Person consent form states that if the participant also wants to withdraw from the telephone component that they must notify Abt SRBI, Inc. either by writing or by telephone. Therefore, a protocol deviation per se did not take place, but the study team recognizes that the participant probably thought he was covered for also withdrawing from the telephone component by speaking on the phone with the in-person study team member on 8/27/2010.

3. Reported to the IRB on March 21, 2011: Five study participants affected are a part of the telephone survey portion of the study through Abt SRBI, Inc (SRBI). At baseline, each of these participants consented during their telephone survey to be contacted for the in-person survey as well. For various reasons, such as non-contact, declined or screen fail, these participants did not enroll into the in-person survey cohort. Therefore, they were no longer to be contacted regarding the in-person survey. At the end of baseline in November 2009, a master list was sent from the UHCMC Coordinating Center to SRBI to identify those participants "not participating" in the in-person survey. SRBI then programmed these participants as "not participating" in their database so they would not contact them in the follow up years regarding the in-person survey. Each week SRBI securely sends the Coordinating Center a list of in-person survey participants that completed this year's telephone survey. On the list received 3/9/2011, these 5 participants 0254, 0234, 0181, 0124 and 0137 were listed, who are not a part of the original in-person cohort and therefore should not have been questioned about their participation in the in-person survey. Upon catching this error on 3/14/2011, the Coordinating Center quickly contacted SRBI to look into the problem and ensure the problem was fixed. It was discovered that there was a problem during SRBI's programming for Year 3 in November 2010. Those participants who did not enroll into the in-person survey during baseline, but missed their Year 2 telephone survey with the appropriate coding, were mis-coded for Year 3 to be contacted about the in-person survey as per the IRB approved protocol. This programming error was fixed on 3/17/2011.
4. Reported to the IRB on July 13, 2011: The one participant affected is enrolled in the original cohort of the Telephone Survey through Abt. SRBI Inc. and the In-person Survey at UHCMC. In November 2010 the Dynamic Cohort began enrolling participants to replenish the original cohort. When Abt. SRBI Inc. received the list of potential Guard members from the Ohio National Guard, there were some duplicates from the original cohort that were discovered and rectified (see previous U/D submission on 1/11/2011). However, when non-contact letters (IRB approved process) were sent out on June 13, 2011 to non-responders in the Dynamic Cohort, 15 of these duplicate cases were erroneously sent the letter by Abt SRBI, Inc. One participant responded to the non-contact letter and completed the dynamic cohort baseline telephone survey. Each week SRBI securely sends the UHCMC Coordinating Center a list of new Dynamic Cohort cases that responded positively to participating in the in-person survey. When the list was sent for the previous week on July 6th, the error was caught by the project coordinator when she this participant from the Dynamic Cohort list was already enrolled in the original cohort of the telephone survey and in-person survey.
5. Reported to the IRB on August 5, 2011: Year 3 interview for participant #0866 was audio recorded on 7/28/2011 after obtaining appropriate informed consent. Prior to removing the audio file from the USB audio recorder to put into the study database, as is typically done when the interviewers return to UHCMC, on Friday 7/29/2011 the interviewer lost the recorder, believed to have been at the Akron Public Library

(where another interview was cancelled that day). The interviewer's bag fell in the parking lot and she believed she collected everything, but upon returning to UHCMC realized that the audio device was missing. However, the audio recorder was found after filing the unanticipated problem, therefore, the submission was updated and no longer a problem.

Protocol Deviations

Over the past year since the last CR, there have been 0 protocol deviations reported to the IRB and DSMB:

Subject Complaints

Over the past year since the last CR, the following 1 complaint was noted by the Coordinating Center at UHCMC and 1 complaint was noted by Abt. SRBI. A Dynamic Cohort Baseline participant, who agreed to be contacted for the in-person interview, was called by the Project Coordinator at UHCMC to discuss possible enrollment into the in-person survey. This participant said that they never received their check from the Telephone Survey; therefore, they were not interested in participating in other areas of the study. As a result, this participant was a screen failure and no longer contacted.

Abt SRBI reported one complaint of a telephone survey participant who did not receive their stipend or the genetics kit that they agreed to receive. This complaint was rectified by sending the check and DNA kit to the participant.

RECRUITMENT/RETENTION PROBLEMS

As reported in the last CR, after obtaining IRB approval for the Dynamic Cohort in August 2010, the investigators worked with the Ohio National Guard to do the first "refresh" sample.

Challenges noted by the Telephone Survey:

As stated earlier, November 2010 began recruitment for the Dynamic Cohort to replenish the original cohort up to 3,000 interviews. Of the 2,440 participants who did not "opt out" of the survey after receiving the alert letter in October 2010, 1,160 (47.5%) of these cases did not have a phone number on record. SRBI was able to locate 799 of these cases through the mail or via an IRB approved search engine method, while 361 (15% of the overall sample) were still unable to be contacted. Letters (template is IRB approved) were sent to these 361 cases requesting updated contact information. Due to the lack of contact information, the telephone survey has thus far fallen short of the goal of 3,000 interviews during Year 3. However, the overall sample for Year 3 including the new dynamic cohort cases is higher than the Year 2 interviews completed, so this is an improvement over last year. SRBI will continue to call Year 3 participants and replenish the cohort until July 2012 as per the protocol-specified window.

Challenges noted by the In-Person Survey:

As stated in the protocol, Abt SRBI, Inc. randomly approached the DC-B participants during their baseline interview about the In-Person Survey and sent positive responses to the Coordinating Center so that the In-Person Survey could be replenished up to 500 completed interviews. In September 2010, UHCMC hired a third interviewer for a total of five project interviewers in hopes to reach 500 without increased burden on the traveling interviewers. However, due to medical leaves of absence across 4 of the 5 interviewers over the past year, we were only at "full strength" with 5 interviewers present for one full month. Therefore, while

it is unlikely that we will reach the 500 completed interviews, the dynamic cohort replenishment has already allowed us to go above Year 2 interviews completed.

The investigators plan to work with the Ohio National Guard during September-October of each subsequent project year to sample newly-enlisted service members, with the goal of replenishing the samples on an annual basis. The investigators still intend to retain as many participants as possible on an annual basis.

Genetics Study

Since starting Genetics Study recruitment in May 2010, the investigators have been closely tracking the return rate of completed consent forms, self-report surveys, and saliva DNA samples. Since implementing the protocol changes approved in the last CR (Amendment 7), the return rate increased from 44% to 53%, and has held steady the past 6 months.

STUDY FINDINGS

Please find attached a **Progress Report** of the data analysis to date.

The Publication Committee became operational in late 2009 for the Initiative, and 1 manuscript has been published over the past year, Calabrese, J. R., Prescott, M., Tamburrino, M., Liberzon, I., Slembariski, R., Goldmann, E., et al. (2011). PTSD comorbidity and suicidal ideation associated with PTSD within the Ohio Army National Guard. *The Journal of Clinical Psychiatry*, 72(8), 1072-1078. Currently, there are 2 manuscripts pending review at peer-reviewed journals, and 1 being written/revised for publication. Additional manuscripts are in the data analysis stage and will be completed as prioritized by the Steering Committee.

RISK/BENEFIT RATIO

The risk/benefit ratio remains unchanged for this mild-risk, non-interventional study. There have not been any relevant publications or data that the investigators are aware of that would affect the risk/benefit ratio of the study.

DATA SAFETY & MONITORING BOARD

Since the last CR, the independent DSMB met on February 7, 2011, May 18, 2011 and September 7, 2011, with the next meeting slated for December 2011. Please see attached letters allowing the study to continue that were submitted to the IRB on File during the year. The DSMB members did not have any recommendations for the study team or reservations about the study proceeding as planned. If any SAEs should occur over the next year, the DSMB Chair, Dr Seagraves, will review in real time. The DSMB will meet quarterly over the next year, provided that there is content to be reviewed (i.e. new survey versions, SAE reports, U/D reports).

TRIAL REPORTS FROM MULTI-CENTER SITES

n/a

CONFLICT OF INTEREST

n/a: There has not been a change in investigator conflict of interest over the past year.

ADDENDA APPROVED OVER THE PAST YEAR:

The following addendum submissions were submitted and approved by the IRB during the past year covered by this review. Please note that only major submissions including an

“Amendment” document, numbered sequentially, and are noted below as applicable. The submissions included the following documents:

1. January 2011 (Amendment 8) #1: The Year 3 surveys were updated after the pilot period. Changes included; survey structure, skip patterns, typos, etc. For the Year 3 In-Person Surveys, the 7/22/2010 version was used for the entire project year. The 1/26/2011 version (post pilot version) UHCMC IRB approval letter was sent on 4/12/2011 by which date over 30% of the Y3 sample had been collected. The investigators decided would overly complicate data analysis to change survey versions at that point in time. The 1/26/2011 versions of the SRS and CRS will be used as the basis for the Year 4 survey development
2. January 2011 #2: Genetics consent form updated to add text box stating that the blue copy is for the participant.
3. February 2011(Amendment 9):
 - a. The Dynamic Cohort Baseline surveys were updated after the pilot period. Changes included; survey structure, skip patterns, typos, etc.
 - b. In-person survey appointment confirmation letter template was updated to add text relating to the electronic version of the SRS for participants to access. .
4. April 2011 #1: Telephone Survey Year 3 survey updated adding additional questions.
5. April 2011 #2: Protocol addendum to add Table 2: Survey Versions.
6. July 2011 (Amendment 10):
 - a. Year 3 Telephone Survey: added text reminding participants that in-person interviewers will travel to a location that is convenient for them, such as their home or nearby public library.
 - b. Year 4 surveys (Telephone, In-Person Clinician Rated and In-Person Self Report)
 - c. In-Person main consent form and verbal consent script/documentation forms: updating publication and consent to re-contact section
 - d. Year 4 memento item: water bottle will be given to all year 4 in-person participants upon completion of their interview.
7. September 2011 (Amendment 10b): submitted on 9/12/2011; awaiting IRB approval (reviewed by full Board 10/18/2011 and requested changes sent to investigators on 10/24/2011)

PLAN FOR UPCOMING YEAR:

- The study team will be contacting all participants who have not exited the study to complete Year 3 in both the Telephone and In-Person Surveys by the end of November 2011 and then proceeding with beginning Year 4 pilot period interviews.
- Internal scientific review for the Year 4 survey development will be implemented in January 2011.
- The Coordinating Center has been working with the BRIC team at MSU on the offline version of the In-Person Survey due to internet connectivity problems that have required interviewers to switch to paper back-up. Current development timelines indicate this will be completed during the first half of 2011. Adequate testing will be completed prior to roll-out with the participants. No changes to the survey contents will be implemented without prior approval of the IRB.
- Please see attached most recent quarterly report to TATRC/USAMRMC (submitted October 14, 2011) which also details upcoming plans for the project.

Kimberly M. Wilson, University of Toledo
NASW Ohio Chapter Annual Conference
Version: 9/23/2010

<http://www.naswoh.org/displayemailforms.cfm?emailformnbr=137001>

Current Word Count: 150
Word Count Limit: 150
Submission Deadline Date: September 30, 2010

Ethics in trauma research: participant reactions to trauma questions in the Ohio National Guard (ONG)

Abstract

There may be concern about iatrogenic harm to participants in studies concerned with history of traumatic event experiences. Although several studies have shown that participants in such research generally appreciate their research engagement and are not harmed by it, this has not been considered in military populations. In-person interviews of ONG members were conducted in the Combat Mental Health Initiative. Axis-I DSM-IV psychopathology was assessed, including PTSD and detailed trauma history. Of 500 participants, 17.2% (n=86) reported being upset by the survey questions at some point during the survey and 7.0% (n=6) of those reported still being upset at the end. Factors associated with increasing the likelihood of participant upset were: history of childhood abuse/neglect ($p<.0001$); suicidal ideation (34%, $p=.001$); female gendered participant (37.3%, $p<.0001$); male-gendered interviewer (24.4%, $p=.0002$); MDD (31.8%, $p<.0001$), GAD (37.5%, $p=.013$), BPD (50.0%, $p=.0023$), alcohol use disorder (21.2%, $p=.0274$), drug use disorder (28.6%, $p=.0045$), and PTSD (61.3%, $p<.0001$). Proportion of participants who reported discomfort with the study questions was in range of, although a bit higher, than that reported in civilian populations. Understanding the determinants of discomfort

in assessments of this population has important implications for work that, over the next few years, aims to study mental health among returning soldiers.

Title: Baseline Results and Validation Methods of a 10 year Longitudinal Study of the Ohio Army National Guard.

Educational Objectives

1. Recognize the importance of screening for alcohol use disorders in individuals who have served in the military.
2. Compare lifetime prevalences of depressive disorders and PTSD in the Ohio Army National Guard (OHARNG) to prevalences in the general population.
3. Understand the reliability and validity findings of the methodology being used in the baseline year of this longitudinal study of OHARNG members.

Abstract

Objective

To explore lifetime prevalence of mental disorders and report reliability and validity findings from the baseline year in an ongoing study of the Ohio Army National Guard (OHARNG).

Method

2616 randomly selected OHARNG soldiers received hour-long structured telephone surveys including PTSD Checklist (PCL-C) and Patient Health Questionnaire – 9 (PHQ-9); a subset (N=500) was randomly selected to participate in 2 hour clinical reappraisals, using the Clinician-Administered PTSD Scale (CAPS) and SCID. Interviews occurred between Nov. 2008 and Dec. 2009, and there was an overall 43% participation rate.

Results

The baseline sample was comparable to the OHARNG overall where the majority were male (85%), white (88%) and enlisted personnel or cadets (87%). Most commonly reported lifetime conditions for the telephone sample were: alcohol abuse 24%, alcohol dependence 23.5%, “any depressive disorder” 21.4%, and PTSD 9.6%. Compared to the CAPS, the telephone survey assessment for PTSD was highly specific (92% (SE 0.01)) with moderate sensitivity (54% (SE 0.09)). The telephone assessment (PHQ-9) of “any depressive disorder” also was very specific (83% (SE 0.02)) and moderately sensitive (51% (SE 0.05)) compared to clinical reappraisals using the SCID. Other psychopathologies assessed on the telephone included alcohol abuse (sensitivity 40%, (SE 0.04) and specificity 80% (SE 0.02)) and alcohol dependence (sensitivity, 60% (SE 0.05) and specificity 81% (SE 0.02)).

Conclusions

Validity and reliability statistics for telephone assessments indicated the methods performed well as research instruments. This ten year longitudinal study is expected to advance knowledge of the trajectories of post-deployment psychopathologies among OHARNG members.

Co-Author(s) Information

Marijo Tamburrino, M.D., Marta Prescott MPH, Joseph Calabrese, M.D., Israel Liberzon, M.D., Renee Slembariski, M.B.A., Emily Goldmann, M.P.H., Edwin Shirley, Ph.D., Thomas Fine, M.A., Toyomi Goto, M.A., Kimberly Wilson, MSW, Stephen Ganocy, Ph.D., Philip Chan, M.S., Alphonse Derus, B.S., Mary Beth Serrano, M.A., James Sizemore, M.Div., Sandro Galea, M.D.

FOR SUBMISSION AS A Scientific and Clinical Report:

Psychiatric Comorbidity in the Baseline Sample of 2,616 Soldiers in the Ohio Army National Guard Study of Combat Mental Health

Joseph R. Calabrese, MD (1), Marta Prescott, MPH (2,3), Marijo Tamburrino, MD (4), Israel Liberzon, MD, PhD (5), Renee Slembariski (1), Emily Goldman, MA, (2,3), Edwin Shirley, PhD (1), Thomas Fine, MA (4), Toyomi Goto, MA (1), Kimberly Wilson, MSW (4), Stephen Ganocy, PhD (1), Philip Chan, MS (1), Mary Beth Serrano MA(1), Sandro Galea, M.D., Dr PH (2,3)

(1) Department of Psychiatry, University Hospitals Case Medical Center, Case Western Reserve University, Cleveland Ohio, (2) University of Toledo Health Science Center, Toledo, Ohio (23) University of Michigan, Ann Arbor, Michigan, (34) Columbia University, NY, NY. (4) University of Toledo Health Science Center, Toledo, Ohio.

Abstract Current Word count - 250

Objective - Study psychiatric comorbidity and suicidal ideation in an ongoing study of soldiers in the Ohio Army National Guard(OANG). **Method** - Of 12,225 soldiers invited, 63% agreed to participate. After collecting military information, we administered the social support module of the Deployment Risk and Resilience Inventory, Life Events Checklist, PTSD Checklist, Patient Health Questionnaire-9, the Generalized Anxiety Disorder(GAD)-7, and the Mini International Neuropsychiatric Interview (alcohol abuse (AA) and dependence (AD). **Results** – Within this random representative sample, 64% had at least one past deployment. The prevalence of PTSD within the past year were 6.88%, depression 13.95%, GAD 2.03%, AA 9.63%, AD 7.00%, and none of the above 63.07%. In soldiers with PTSD, GAD was 20 times more likely to have occurred within the past year compared to those without (OR 20.36; 95% CI 11.39-36.38), depression 7 times (OR 7.39; 95% CI 5.4–10.11), AD 3 times (OR 3.02 95% CI 1.99–4.58), and very highly increased risk for having at all 3 conditions (OR 60.86, 95% CI 17.33–213.78); 67% had previously sought help through a professional or a self help group. In soldiers with current PTSD accompanied by at least 2 comorbidities, suicidal ideation (which was present in 62% overall) was 7 times more likely to occur (OR 7.46; 95% CI 3.05-18-26). **Conclusions** - These findings suggest that soldiers with PTSD frequently have a co-occurring mental health condition and a history of suicidal ideation, which highlights the complexity of this patient population and the magnitude of associated human suffering.

Funding Source: Department of Defense Congressionally Directed Medical Research Program: W81XWH-O7-1-0409, the 'Combat Mental Health Initiative'.

Conflicts of Interest: none

Title: Baseline Results and Validation Methods of a 10 year Longitudinal Study of the Ohio Army National Guard.

Primary Topic

Epidemiology

Secondary Topic

PTSD

Educational Objective

At the conclusion of this session, the participant should be able to recognize the importance of screening for alcohol use disorders, depressive disorders and PTSD in individuals who have served in the military.

Abstract

Objective

To explore lifetime prevalence of mental disorders and report reliability and validity findings from the baseline year in an ongoing study of the Ohio Army National Guard (OHARNG).

Method

2616 randomly selected OHARNG soldiers received an hour-long structured telephone survey including the PTSD Checklist (PCL-C) and Patient Health Questionnaire – 9 (PHQ-9); a subset (N=500) was randomly selected to participate in 2 hour clinical reappraisals, using the Clinician-Administered PTSD Scale (CAPS) and SCID. Interviews occurred between Nov. 2008 and Dec. 2009, and there was an overall 43% participation rate.

Results

The baseline sample was comparable to the OHARNG overall where the majority were male (85%), white (88%) and enlisted personnel or cadets (87%). The most commonly reported lifetime conditions for the telephone sample were: alcohol abuse 24%, alcohol dependence 23.5%, “any depressive disorder” 21.4%, and PTSD 9.6%. Compared to the CAPS, the telephone survey assessment for PTSD was highly specific (92% (SE 0.01)) with moderate sensitivity (54% (SE 0.09)). The telephone assessment (PHQ-9) of “any depressive disorder” also was very specific (83% (SE 0.02)) and moderately sensitive (51% (SE 0.05)) compared to the clinical reappraisal using the SCID. Other psychopathologies assessed on the telephone included alcohol abuse (sensitivity, SE 40% (0.04) and specificity, SE 80% (0.02)) and alcohol dependence (sensitivity, SE 60% (0.05) and specificity, SE 81% (0.02)).

Conclusions

Validity and reliability statistics for the telephone assessments indicated the methods performed well as research instruments. This ten year longitudinal study is expected to advance knowledge of the trajectories of post-deployment psychopathologies among OHARNG members.

Co-Author(s) Information

Marta Prescott MPH, Joseph Calabrese, M.D., Israel Liberzon, M.D., Renee Slembariski, M.B.A., Emily Goldmann, M.P.H., Edwin Shirley, Ph.D., Thomas Fine, M.A., Toyomi Goto, M.A., Kimberly Wilson, MSW, Stephen Ganocy, Ph.D., Philip Chan, M.S., Alphonse Derus, B.S., Mary Beth Serrano, M.A., Sandro Galea, M.D.

Literature References

Vogt DA, Samper RE, King DW, King LA, Martin JA: Deployment stressors and posttraumatic stress symptomatology: comparing active duty and National Guard/Reserve personnel from Gulf War I. *J Trauma Stress* 2008; 21:66-74.
Hoge CW, Castro CA, Messer SC, McGurk D, Cotting PI, Koffman RL: Combat duty in Iraq and Afghanistan, mental health problems and barriers to care. *N Engl J Med* 2004; 351:13-22.

ABSTRACT**Risky driving behavior among Ohio Army National Guard soldiers****Hoggatt KJ, Goldmann E, Prescott M, Calabrese J, Tamburrino MJ, Liberzon I, Galea S**

Nearly half all forces engaged in the recent wars in Iraq and Afghanistan were reserve forces and there is an increasing reliance on national guard soldiers in combat. Although there is emerging evidence of long term behavioral disorders after deployment among these forces, we know little about health risk behavior, such as risky driving, among national guard soldiers. We recruited 2616 Ohio Army National Guard soldiers, 1294 of whom had been deployed and experienced at least one traumatic event during the most recent deployment. Overall, 12% reported drinking and driving within the past 30 days, 26% reported passing cars on the right often within the past year, and 25% reported ignoring speed limits during the night or early morning often within the past year. Mental health (PTSD, generalized anxiety disorder, major depression) and alcohol abuse or dependence were associated with increased risky driving. In men, alcohol abuse or dependence predicted risky driving (drinking and driving: odds ratio (OR) and 95% confidence interval (CI) = 7.5 (5.0, 11.4); passing on the right: 2.5 (2.0, 3.1); ignoring speed limits: 2.2 (1.8, 2.7) even after controlling for mental health history, deployment, and demographic characteristics. Results for women were similar. Deployment was associated with risky driving for men (OR (95% CI): 1.6 (1.1, 2.3) for drinking and driving, 1.6 (1.2, 2.1) for passing on the right, and 1.2 (0.9, 1.6) for ignoring speed limits). Among recently deployed men, risky driving increased with the number of traumatic events experienced. Post-deployment support of reserve forces, particularly those who have seen combat, should include attention to potential for health risk behavior such as risky driving.

Area topic: Psychiatric epidemiology

Title of Paper: Mental health disorders increase the risk of during and post-deployment alcohol abuse among Ohio Army National Guards

Conference: International Society for Traumatic Stress Studies 27th Annual Meeting

Presentation Type: Oral/Poster Presentation

Submitted By: Brandon DL Marshall, PhD
Department of Epidemiology
Columbia University Mailman School of Public Health
722 W 168th Street
New York, NY, 10032-3727
Tel: 212-305-2433
E-mail: bdm2125@columbia.edu

Authors: Brandon DL Marshall, Marta R Prescott, Joseph R Calabrese, Marijo B Tamburrino, Israel Liberzon, and Sandro Galea

Presented By: Marshall BDL

Background: Alcohol use disorders are common in military personnel; however, it is not clear if mental health conditions increase the risk of during and post-deployment alcohol abuse among this population.

Methods: Ohio National Guards were randomly selected to complete computer-assisted telephone interviews between June 2008 and February 2009. The primary outcome was reporting alcohol abuse meeting DSM-IV criteria first occurring during or post-deployment. Primary exposures of interest included during-/post-deployment major depressive disorder (MDD) and posttraumatic stress disorder (PTSD). Predictive logistic regression was used to determine the independent correlates of during-/post-deployment alcohol abuse.

Results: Of 963 deployed participants, 113 (12%) screened positive for during-/post-deployment alcohol abuse, of whom 35 (34%) and 23 (33%) also reported during-/post-deployment MDD and PTSD, respectively. In a multivariate model MDD (adjusted odds ratio [AOR] = 3.89, 95%CI: 2.12-7.15, $p<0.001$) and PTSD (AOR=2.73, 95%CI: 1.37-5.42, $p=0.004$) were associated with alcohol abuse. The conditional probability of during-/post-deployment alcohol abuse was 7%, 16%, 22%, and 43% among those with no MDD/PTSD, PTSD only, MDD only, and both PTSD and MDD, respectively.

Conclusions: We observed a high prevalence of during-/post-deployment alcohol abuse among Ohio National Guards. Concurrent mental health conditions were highly predictive of developing alcohol abuse, and thus may constitute an etiologic pathway through which deployment-related exposures increase the risk of alcohol problems.

Count: 211 words, 1397 characters (max. 1400 characters)

Panel Presentation: Identifying predictors of trauma response: State of the art of current prospective studies of PTSD

Psychiatric Comorbidity in the Baseline Sample of 2,616 Soldiers in the Ohio Army National Guard Study of Combat Mental Health

DESCRIPTION

Section 1: Primary Purpose or focus of the panel.

Study psychiatric comorbidity in the baseline sample of an ongoing long-term study of soldiers in the Ohio Army National Guard (OANG).

Section 2: Experimental design or Methods used.

Of 12,225 soldiers invited, 63% agreed to participate. After collecting military information, we administered the social support module of the Deployment Risk and Resilience Inventory, Life Events Checklist, PTSD Checklist, Patient Health Questionnaire-9, the Generalized Anxiety Disorder (GAD)-7, and the Mini International Neuropsychiatric Interview section on alcohol abuse (AA) and dependence (AD). Assessment tools were tested in clinical re-appraisal.

Section 3: Summary of results.

Within this random representative sample, 64% had at least one past deployment and the prevalence of PTSD within the past year were 6.88%, depression 13.95%, GAD 2.03%, AA 9.63%, AD 7.00%, and none of the above 63.07%. In soldiers with PTSD, GAD was 20 times more likely to have occurred within the past year compared to those without (OR 20.36; 95% CI 11.39-36.38), depression 7 times (OR 7.39; 95% CI 5.4–10.11) and AD 3 times (OR 3.02 95% CI 1.99–4.58). Soldiers with PTSD were also at high risk for having had all 3 conditions (OR 60.86, 95% CI 17.33–213.78) and 67% had previously sought help through a professional or a self help group.

Section 4: Conclusion statement.

These findings suggest that while the OANG are facing as much combat as the regular army, in cross-study comparisons, it appears that they are rather resilient to mental health conditions common after combat exposure. For those who do have PTSD, they almost always have a co-occurring mental health condition, which highlights the complexity of this population and the magnitude of their unmet clinical need. Participants are administered the survey annually in order to study the longitudinal trajectory of psychopathology.

UNIQUE DATA

In a representative sample of National Guard soldiers we found that soldiers with PTSD were more likely than soldiers without PTSD to report suicidal ideation and that among those with PTSD, comorbidity with more than one disorder was associated with a substantially higher risk for suicidal ideation. The association between PTSD and suicidal ideation in the National Guard adds to the growing evidence of this association in military populations. The data is unique as no other projects have focused on the National Guard or non-treatment seekers outside of the veteran's administration.