PROJECT TITLE: Survey of OIF/OEF Veterans' Clinical Needs and Preferences: A Pilot Study

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A. RATIONALE

1. Problem

Veterans returning from service in Iraq and Afghanistan are providing new challenges to VHA and other healthcare systems. Increasing evidence suggests that veterans of Operation Enduring Freedom and Operation Iraqi Freedom (OEF/OIF) differ in significant ways from veterans of previous conflicts. Soldiers currently serving in Iraq and Afghanistan constitute the most diverse military population our country has seen to date (1). Women constitute approximately 16% of all active duty personnel. Ethnic minorities range from 24% to 40% in the various armed services. Most (over 95%) have earned a minimum of a high school education. The high prevalence of National Guard and Armed Forces Reserve Units (Reserve component) in these conflicts is resulting in an older, more educated armed forces population, with experiences pre- and post-deployment that often differ from traditional Active Duty components.

High rates of mental health concerns and debilitating sequelae of traumatic brain injury (TBI) have been reported in this cohort (2-3). Even more of these veterans are experiencing post-deployment adjustment issues including difficulties with irritability and anger, family conflicts, and interpersonal difficulties, with those most in need of mental health services reporting the most concern about stigma and negative consequences for seeking help (3). The Department of Defense (DoD) and the Veterans Health Administration (VA) have partnered to attempt to address these issues earlier than such attempts have been made following past conflicts. The DoD has described successful use of Combat Stress Control Units in the field to provide support following combat trauma and to promote recovery and return to duty. The VA has committed to provision of 2 years of priority healthcare for deployment-related conditions for National Guard and Reservists and separated Active Duty military personnel returning home from combat deployment. Understanding the health-related concerns, needs and preferences of recently deployed veterans is critical in order to provide them with comprehensive quality healthcare and potentially to prevent chronic problems through timely, efficacious and compassionate care.

The primary aim of this project is to assess the health needs, concerns and preferences of OEF/OIF veterans in VISN 6. Importantly, this study seeks to solicit information from both VA users and nonusers, with the understanding that OEF/OIF veterans may become users of VA healthcare sometime during their 2 year window of priority eligibility, or later for treatment of service-connected conditions. An additional aim is to pilot the survey instrument that has been developed to incorporate both relevant standardized measures and new relevant information collected during our completed series of focus groups with OEF/OIF veterans and their families. Finally, response rates to mailed surveys have been lower among this population compared to the VA population at large. We will examine survey response rates with and without a mailed letter sent in advance of the survey, to determine best strategies for optimal response rates in this cohort of mostly younger veterans.

Results from this project will be used to further tailor VA services and educational products for OEF/OIF veterans and their families, and to advise and guide VA efforts to develop a standardized OEF/OIF needs assessment survey for a national study.

2. Research Questions

The primary research questions for the study are:

(R1). What are the mental and physical health problems or concerns of returning OEF/OIF veterans in VISN 6?

(R2). What is the prevalence of potential health risk behaviors in this cohort?

(R3). What are the perceived barriers to care for deployment-related issues and preferences for services and information among these veterans?

3. Objectives

a. Short-term objectives (one year)

Data from this comprehensive 8-page mailed survey of a random sample of 5,000 VA-eligible OEF/OIF veterans in VISN 6 will guide current clinical and educational program development and will be disseminated to interested local and national stakeholders. Response rates will be compared between demographic groups (e.g., gender, race, age) to assess potential response bias.

b. Long-term objectives (future study)

Survey results will be examined to determine needs, preferences, and barriers to care among subgroups of veterans, including women and reserve component veterans, for future targeted interventions. The survey and results will be shared with the national VA workgroup currently developing OEF/OIF standardized assessments for a collaborative survey study.

4. Current Status of Work in the Area

Current knowledge of the health needs and barriers to care of OEF/OIF veterans is limited. There have been initial reports that a substantial number of these veterans have significant mental health concerns (2-4). In a survey of over 3600 veterans after combat duty in Iraq or Afghanistan, Hoge and colleagues (2) report that 15-17% of veterans met screening criteria for major depression, generalized anxiety disorder, or posttraumatic stress disorder (PTSD). Post-deployment health assessments have suggested that 19% of service members returning from Iraq reported mental health problems, although thirty-five percent of Iraq war veterans reported accessing some type of DoD mental health services in the year following their return home (3). Twelve percent of these veterans were diagnosed with a mental disorder. Despite high rates of mental health symptoms reported among OEF/OIF troops, however, initial evidence suggests that only a small percentage of those screening positive for mental disorders are receiving help from a mental health professional (2). In a more recent report, up to 17% of soldiers screened positive for PTSD one year after return from combat duty in Iraq, and PTSD was associated with lower general health ratings as well as more missed workdays, more physical symptoms and higher somatic symptom severity (4).

Very little is known about the physical health complaints or concerns of OEF/OIF veterans. Although there have been news reports of concerns over environmental exposures, the empirical literature to date is lacking. The War Related Illness and Injury Study Center in New Jersey conducted a retrospective chart review of all OEF/OIF patients evaluated in their specialty clinic between June 2004 and June 2006 (5). They found that over half had mental health concerns, usually PTSD, and common exposure concerns included depleted uranium,

multiple vaccinations and poor air quality. Physical complaints in this convenience sample primarily involved the musculoskeletal system or eyes nose and throat (5). Among VA users nationally, the most common health problems have been musculoskeletal ailments, mental disorders, and ill-defined conditions, which includes symptoms not yet associated with a specific diagnosis (6). There is currently little information about the health needs or concerns of non-VA users. Similarly there is almost no published data regarding the perception of VA services and barriers to healthcare access among this cohort. Similarly, there are limited published reports on the impact of these issues on veterans' families.

5. Significance of Proposed Research

Systematic studies are needed to assess both the mental health and physical health needs of OEF/OIF veterans to inform policy related to the optimal delivery of health care to these returning veterans. Improved continuity of care is a key issue for this veteran population, as has been indicated through recent VA complaint analyses and increasing roles for Seamless Transition staff bridging the DoD and VA continuum of care. This research is an important step in the incorporation of the veteran's perspective in the development of VA healthcare services and related partnerships with DoD and community support sources.

6. Relevance of Proposed Work to VA patient Care Mission

This work is extremely relevant to VHA as it is expected to serve as a major provider of care for OEF/OIF veterans. Of the 686,306 OEF/OIF troops returning to civilian life by early January 2007, 229,015 (33%) have sought health care from VA since 2002. Of these, about 3% have been hospitalized at least once in VA, and 83,889 (37%) have received a mental disorders diagnosis (6). Of this latter group, 39,243 (47%) met criteria for PTSD and 26,998 (32%) met criteria for tobacco use disorder. Actual prevalence of mental health and substance use disorders may be higher among VA users. A recent study of mental health care needs among OEF/OIF returnees estimated that only10% of help-seeking veterans have a recorded diagnosis of PTSD (7). Data collected on the mental and physical health needs and concerns of OEF/OIF veterans and the barriers to the access of VA care will inform VA policy on the delivery of care to these veterans.

B. BACKGROUND AND WORK ACCOMPLISHED

The Mental Illness Research, Education and Clinical Center (MIRECC) is an organization within the Department of Veterans Affairs (VA), Mid-Atlantic Veterans Integrated Service Network (VISN 6), Mental Health Service Line (MHSL). The VISN 6 MIRECC is organized as a translational medicine center in which the overarching goal is the clinical assessment and treatment of post-deployment mental illness. The MIRECC's organizational structure includes four major components: Clinical, Research, Education, and Evaluation. The current project is being conducted by investigators in the Clinical and Health Services Research components.

Our group has extensive experience assessing the physical and mental health concerns and service utilization of veterans (8-14) and conducting survey research (15). In addition, we have investigated other important sequelae of combat-trauma including anger and aggression (16), suicidality (17), substance use (18) and problems facing families of veterans with severe mental illness (19). Investigators from our group co-led the development of the North Carolina Governor's Summit on Returning Veterans and their Families, in collaboration with state Department of Health and Human Services Secretary Odom and mental health leaders from state government, DoD, and local and national service organizations (21). Our group co-led the joint DoD/VA Conference on Post-Deployment Mental Health (22). This conference of VA and DoD stakeholders and policy makers concluded that all veterans and their families are affected

by their deployment experiences. It was agreed that most veterans will experience normative post-deployment adjustment problems including problems with irritability and anger, family conflict, and employment difficulties and a significant proportion will have mental health problems that will require clinical attention. It was concluded that more information is needed regarding the clinical needs of this important veteran cohort and the barriers that limit their access and utilization of care.

While it is becoming clear that there are considerable mental health needs among these veterans, practical experience and a recent survey of active duty military about their attitudes toward seeking care for mental health needs have revealed significant barriers to help seeking among this population including fears of stigmatization and job-related concerns. Our experience with a recent unpublished quality assurance project at the DVAMC PTSD Clinic found significant barriers to the access of mental health services. In the DVAMC PTSD Clinic, 40% of OEF/OIF veterans referred by primary care providers for specialty Mental Health assessment and treatment have failed to access these services. In telephone follow-up of these veterans, logistical barriers to accessing care (e.g., concerns about taking time off from jobs the veterans may have only recently been hired for in order to attend VA appointments; or family obligations for these recently reunited families) have been reported most often as an explanation for missed appointments or for refusal to engage in even brief therapies. A more thorough assessment of barriers to care is needed in order to develop effective outreach and interventions for this cohort.

C. Work Proposed

1. **Study Design.** This cross-sectional research pilot study will survey a random sample of 5,000 of the estimated 70,000 OEF/OIF veterans eligible for VA services and residing in the VISN 6 catchment area (6).

2. **Participant Identification**. Participants will be randomly selected from a DoD list of separated active duty personnel and National Guard/ Reservists who have served in support of Iraq and Afghanistan. This list is updated monthly by the DoD's Defense Manpower Data Center (DMDC) and is maintained confidentially by Dr. Han Kang of the VA Environmental Epidemiology Service in Washington, DC. Inclusion criteria for random selection of our sample includes: history of OEF/OIF military service according to the DMDC roster list; and last known residence in the VISN 6 catchment area. Prior to finalizing and releasing the sample, Dr. Kang's list is checked against BIRLS death data to exclude deceased veterans. This list of 5,000 veterans' names , addresses, and available demographic information (age, race, gender, branch of military, unit-type) will be saved on a password protected CD and delivered via Federal Express to the survey contractor, Schulman, Ronca, & Bucuvalas, INC (SRBI), now called Abt SRBI, which has signed a Business Associate Agreement (BAA) and VA contract. All Abt SRBI project staff have completed mandated human subjects and VHA data security and privacy training, as well as scope of practice and conflict of interest forms. At no time will the VA investigators have access to the identities of survey responders or nonresponders.

3. **Procedure**. All survey procedures will be conducted by the contract research organization, Abt Schulman, Ronca, & Bucuvalas, INC (Abt SRBI). Abt SRBI is an independent survey research organization that specializes in health care research with nearly 3 decades of experience in conducting veteran research. Most recently Abt SRBI has completed a post-deployment (contract) study with VISN 5 and the VA Office of Public Health and Environmental Hazards, which closely parallels our proposed project. Per VA policy, Abt SRBI has signed both a contract and business associate agreement (BAA) with the VHA that assures protection of protected health information (see attached BAA).

3.a.Data Collection Methods

Data collection will follow a modified Dillman Total Design Method approach to survey research (23). All participants will receive a pre-alert letter, a survey package and if needed, a follow-up letter and duplicate survey.

A pre-alert letter will be sent one week prior to the initial mailing of the survey package. The letter will let the veteran know that the study's results will be used to improve VA services for OEF/OIF veterans and their families and will help VA better understand their needs and preferences (see Advance Letter, attached).

The survey package will include a cover letter, the survey instrument and a postage-paid business reply return envelope addressed to Abt SRBI. The cover letter from the Co-Principal Investigators will contain an explanation of the study. The cover letter will contain elements of informed consent, assurance of the anonymity of their responses and contact information for both Abt SRBI and VA investigators, should the recipient want more information by telephone. VA contact information for healthcare and benefits will also be included. The questionnaire will be formatted for ease of self administration and printed in 3 colors.

Surveys will contain an ID number which will allow Abt SRBI to determine which participants returned the survey. If the survey has not been received within 5 weeks of the initial mailing, participants will be sent a follow-up letter and duplicate survey. The letter will thank them for their time and will prompt them to return the completed survey if they have not yet done so.

If upon 5 weeks after the final mailout, a survey has not been received by Abt SRBI, the participant will be coded as a non-respondent. Abt SRBI will then destroy the link between the survey barcode and the respondent. At this point, there will be way to link an individual's responses back to their identity. Thus, the data obtained by the VA investigators will be completely anonymous.

3.b. Survey Measure

The 8-page survey (attached) contains items from standardized screening and assessment measures for depression, PTSD, substance abuse, traumatic brain injury (TBI) and other medical symptoms and conditions. Additional topics assessed include: sources of healthcare and support, preferences for new services and information, satisfaction with healthcare and general demographic and military service data. The survey has been reviewed and is pending final approval by the U.S. Office of Management and Budget (OMB). A final OMB approval number will be printed on the survey as required by the Paperwork Reduction Act of 1995.

4. Data Management and Analysis. Abt SRBI has a variety of mail production and optical scanning equipment to conduct mail surveys. This includes a CS Optical Scan 4 that has a throughput rate of 2,000 sheets per hour with a dual side read in a variety of page sizes. Data is automatically converted to an SPSS readable dataset for analysis.

4a. Data Entry

Once OCR (Optical Character Read) mail questionnaires have been logged-in, the questionnaire will be reviewed for completeness, legibility (readable markings), and whether or not it is in good enough shape to be scanned. The information from returned questionnaires that have been folded, crumpled, ripped, etc., to a point where they will not be read by the scanner will be transferred to a blank form so that it can be included in the final data set.

After a form has been scanned it will have all of the responses to "Other, specify" response categories, if any, transcribed. Only the questionnaire number will identify these responses.

At no time will the VA study investigators be able to link any response to a specific person. The ASCII data file prepared in the scanning process will be automatically converted to an SPSS data set. Once in an SPSS format, the data will go through an editing process ensuring that all skip patterns are followed. While it is possible to eliminate responses to questions that should not have been answered, it is impossible to do anything about missing answers to questions that should have been answered.

4b Data and Documentation

At the conclusion of the project, Abt SRBI will deliver to MIRECC VA investigators, Drs. Straits-Troster and Calhoun, a final data set with no participant identifiers on a CD containing all of the edited main survey data. No information that could link an individual back to his or her responses will be included. Thus, the dataset will not contain names, addresses or other geographic information, dates, or other unique identifying characteristic.

Abt SRBI will destroy all of their related data within 6 months of the completed administration of the survey and delivery to investigators, per contract.

Additionally Abt SRBI will provide:

- A fully-annotated and comprehensive methods report prepared by the project director;
- A hard copy marginal dump of the data set;
- Documentation and file layout; and
- Code books, relevant completion records, any weighting instructions and all other similar documentation materials.

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4c. Data Analysis

Data will be cleaned and summarized. Logistic regression will be used to examine potential response bias between racial, gender, age, and military unit type groups (e.g., active duty versus reserve/national guard). Descriptive statistics will used to characterize participant demographics and prevalence of physical and mental health symptoms. Prevalence of health risk behaviors (smoking, overweight, hazardous alcohol use, drug use, aggressive driving and seat belt) use will be estimated and group differences will examined in unadjusted (chi-square and analysis of variance) and adjusted analyses (multiple and logistic regression). Preferences for healthcare convenience, services most likely to be used, and information sources will be rank ordered by frequency of endorsement. Sample

size will permit comparisons of key variables by gender and active duty vs. reserve component military status.

RESOURCES

E. HUMAN SUBJECTS

1. Risk to Subjects

(a) **Human Subjects Involvement and Characteristics**: OEF/OIF veterans living in the VISN 6 catchment area will be eligible for random selection of the study's OEF/OIF sample cohort. Based on similar surveys with the proposed methodology with this population, Abt SRBI estimates that 55% to 60% (n= 2,750 to 3,000) of the potential 5,000 participants will complete and return the anonymous survey.

The VA investigators will at no time have access to any of the 18 patient identifiers characterizing Personal Health Information (PHI), and thus this protocol is not subject to HIPAA.

(b) **Sources of Materials**: The primary data are the survey responses which will be recorded in a method that will ensure there is no way to link responses back to an individual. Specifically, Abt SRBI will destroy the link between identifiers and participants so that data obtained will be completely anonymous.

(c) **Potential Risks:** There are no known psychological hazards or risks associated with completing surveys, and anonymous surveys are typically exempt from IRB review. It is possible that responding to questions about emotional and physical symptoms and related general military experiences could cause some mild discomfort in the form of a temporary increase in anxiety. All participants will be given contact information for the co-principal investigators and the VA seamless transition website, should they have any questions about the study or post-deployment healthcare services.

2. Adequacy of Protection from Risks

(a) Abt SRBI staff have completed VA research ethical human subjects training (GCP) and VA Research Data Security and Privacy training. Participants will be informed that their participation is entirely voluntary and that their choice to participate or not will have no impact on their clinical care or any other benefits. The contract research company has also supplied a document outlining specific data security and procedures for VA mail surveys in compliance with current VA security priorities and procedures and for use with their other VA contracts. (See "SRBI Data Security and Procedures for Protecting Confidentiality on VA Mail Surveys, attached).Abt SRBI is aware of and follows all federal rules and guidelines that apply to research.
(b) Protection Against Risk: The survey that will be sent to participants will only contain an Abt SRBI ID number and does not ask for respondents to identify themselves in any way. The ID number printed on the survey will be linked to an administrative database that will allow Abt SRBI to determine who responded to the survey. This information will be kept separately from survey response data.

Abt SRBI will not share the link between an individual and his/her responses. Further, they agree to destroy the link following completion of data collection so that data obtained will be completely

anonymous. Upon completion of survey data collection, all data will be transferred to the Durham VA where it will be kept on a secure VA server. Abt SRBI will destroy all copies of any data obtained as part of this project.

3. Potential Benefits of the Proposed Research to the Subject and Others

There are no benefits to the individual participant and no immediate benefits of the proposed research to others. There are potential benefits to others from the information generated that potentially will be helpful in developing health policy to ensure that the mental and physical health needs of this important cohort are met. There is little risk associated with participating in survey studies. In our opinion, the anticipated benefits of this study outweigh the potential risks.

4. Importance of the Knowledge to be Gained

The information gained from these studies will not benefit the volunteer participant, but will help further our knowledge of the health concerns and needs and barriers to care of OEF/OIF veterans and their families. Knowledge gained in this study may be of value in policy development and future survey research and clinical intervention studies.

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