

AD _____

Award Number: W81XWH-08-2-0066

TITLE: Addressing the Needs of Children and Families of Combat Injured

PRINCIPAL INVESTIGATOR: Dr. Stephen Cozza

CONTRACTING ORGANIZATION: Henry M. Jackson Foundation
Rockville, MD 20852

REPORT DATE: April 2011

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for public release; distribution unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.					
1. REPORT DATE (DD-MM-YYYY) 01-04-2011		2. REPORT TYPE Annual		3. DATES COVERED (From - To) 31 MAR 2010-30 MAR 2011	
4. TITLE AND SUBTITLE Addressing the Needs of Children and Families of Combat Injured				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-08-2-0066	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Dr. Stephen Cozza E-Mail: scozza@usuhs.mil				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Henry M. Jackson Foundation Rockville, MD 20852				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT Data collection for this project has begun at WRAMC. The required personnel has been hired at BAMC and recruitment is underway for hiring at Fort Stewart. IRB revisions will be done to expand the inclusion criteria to include younger children and a greater length of time post injury or deployment. An additional means of data collection (via the internet) is being introduced in order to provide more options for subjects as well as to facilitate data collection at a distance.					
15. SUBJECT TERMS Combat injury, families, children, service members, distress, injury communication, parenting, assessment, adjustment					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (include area code)
			UU	6	

TABLE OF CONTENTS

	<u>Page</u>
INTRODUCTION.....	5
BODY.....	5
KEY RESEARCH ACCOMPLISHMENTS.....	6
REPORTABLE OUTCOMES.....	6
CONCLUSION.....	7
REFERENCES.....	7
APPENDICES.....	7

INTRODUCTION:

This investigation focuses on measuring the impact of parental combat injury on military children and families. The study is a longitudinal design comparing families of combat-injured service members (CI group) and non-injured service members (NI group) across a 12-month time-frame. The CI group will be comprised of 200 injured service members and their spouses with at least one child between the ages of 3 and 18 years recruited from WRAMC and BAMC within the first 6 months of hospitalization. The NI group will be comprised of 200 active duty non-injured combat veterans (matched with CI participants for combat experience and relevant demographic factors) and their spouses with at least one child between the ages of 3 and 18 years recruited within 6 months of returning from deployment. Families will be assessed using self-report questionnaires and, for the CI Group, record review of a semi-structured interview currently used at clinical sites. Consenting parents and assenting children ages 6 to 18 years will complete questionnaires assessing the following domains: parental trauma exposure history, symptoms, and function; child traumatic exposure history, symptoms and function; parenting behaviors; and family functioning. Follow up assessments of parental symptoms and functioning, child symptoms and functioning, parenting behaviors, and family functioning will be completed 6 and 12 months after the initial assessment. For families who are not available to complete in-person assessment at 6 and/or 12 months, assessment will be conducted by telephone and measures will be administered verbally. Families will also be briefly contacted at 3 months and 9 months to check-in and inquire whether they are in need of additional resources.

BODY:

Below is a summary of the major activities undertaken by project team members during the last 12 months organized by the timeline in the Schedule of Work (SOW):

1. **Program personnel recruitment and hiring:** In process. Ms. Mona Mendelson, LCSW, the Research Clinician at WRAMC began work on March 1, 2010. Details of her progress at WRAMC follow below. Hiring for a parallel position at BAMC has been accomplished with Dr. Yolanda Rodriguez-Escobar taking the position in January, 2011. Finally, we have posted the position for a Research Clinician at Fort Stewart and have worked with local mental health personnel to help identify appropriate applicants. One candidate for this position has been invited to USUHS for an on-site interview in June.
2. **Staff and clinician training:** Dr. Roderiguez-Escobar completed the required CITI training, HJF orientation, and training related to other job “start up” requirements such as review of protocol and study measures. She came from BAMC to USUHS to meet with the PI and Ms. Mendelson, who took her to WRAMC for an overview of how the data is collected at that site.
3. **Organization and Preparation:** Maintained contacts with WRAMC and BAMC personnel via a monthly telephone call. BAMC PIs and Dr. Escobar participate in these calls in addition to CSTS personnel. To support recruitment activities, Ms. Mendelson created a booklet that includes a description of the study, required subject consent forms, the questionnaires, recruitment flyer, study inclusion criteria and referral script that could be used by WRAMC professionals who might identify potential qualified subjects. A copy of this document has been shared with Dr. Escobar for adaptation to the BAMC site with key hospital staff.

4. **Site Approval and Planning:** IRB approval has been obtained for USU, WRAMC and BAMC. Due to changes in personnel and departure of our previous site PI, Dr. Erin Field has agreed to become the new site PI. Dr. Field is highly qualified as a child psychologist to participate and serve as site PI. Her name has been added to the protocol and this is pending IRB approval.
5. **Finalize Plans:** Plan to hire Fort Stewart personnel and determine the best means of collecting data at that site in a timely manner. Plan to expand inclusion criteria of subjects in order to increase sample size. Complete IRB modifications as required.
6. **Participant Enrollment and Data Collection:** Unfortunately data collection has been slower than anticipated at the three clinical sites. Details are described below. However, it is important to note that at least at WRAMC, over half of those who meet study criteria for inclusion agree to participate in the project, suggesting that low numbers are not associated with study recruitment strategies or requirements.

Specifically, at WRAMC, 11 initial interviews have been completed with eligible injured service members, spouses and appropriately aged children. Seven month follow-ups at the three month mark have also been conducted. As of 4/16/11, 1 six-month follow-up has been completed. We have been tracking causality rates and believe some of the low number of injured reflect the winter in Afghanistan when there is less troop engagement. In addition, given their other duties, shift in mission and the BRAC move to NNMC, may have affected the priority of WRAMC personnel to externally directed projects such as this.

At BAMC, it has taken longer than anticipated to identify and hire a qualified Research Clinician. As noted above, we have finally been successful and the research clinician is now prepared to recruit subjects. She has met frequently with the Site PI's and they have set up a number of meetings with potential referral professionals and are conducting information sessions about the project.

At Fort Stewart, we have had two changes in site PI's which has delayed our data collection efforts. Ft. Stewart personnel were concerned with the impact of the study on their own mission and use of staff time. However within the last two months, Dr. Erin Field has agreed to coordinate the on-site data collection and is planning to create an local research team to assist with recruitment of subjects. Finally, despite extensive efforts in advertising and networking, it has proven more difficult than expected to identify a Research Clinician to conduct the data collection. Fortunately, as of the end of May, we have two promising candidates, one of whom is coming to USUHS for a face to face interview. Thus, once the change in site PI is finalized, Research Clinician hired and IRB changes reflecting these changes are completed data collection can begin at Ft. Stewart.

7. **Problem Areas:** First, IRB approval timing contributed to the delay in beginning data collection (as described above).

Second as already noted, difficulty in identifying appropriate Research Clinicians at BAMC and Ft. Stewart has delayed data collection. Further, the change in site PI at Ft. Stewart has also complicated our ability to make progress.

Third, the number of families who meet current study inclusion criteria is lessening due to changes in the number of combat injured service members returning to CONUS. Also, those potential subject families who otherwise would qualify for enrollment are parents of very young children (younger than the current inclusion criteria). These demographics have shifted some from the time of the original pilot work that informed this project. In order to include these younger families in the study, we requested in April, 2011, a change from our grant funder to include families with very young children and to extend the length of time since injury/hospitalization (up to two years) rather than the current 6 months.

KEY RESEARCH ACCOMPLISHMENTS:

In addition to collecting data on eleven combat injured families (as well as several follow-up assessments of these individuals) we have created a new option (approved by the IRB) of collecting questionnaire data from family members at a distance from the hospitals. We will offer them the opportunity to complete assessments online (CombatInjuryFamilyStudy.com) in addition to in to the existing option of in person or by telephone. The online option will be especially useful for the longitudinal follow-up assessments when it is more likely the families will be leaving the areas of WRAMC, BAMC and Fort Stewart.

REPORTABLE OUTCOMES:

At this point, we have growing data from WRAMC combat injured families. Clinical observation suggests a high degree of family distress. Common issues mentioned were feelings of displacement, being separated from their support systems and difficulty adjusting to living in apartments versus private homes. Evidence of this distress is seen in the legal separation of one couple reported during the three month follow-up.

CONCLUSION:

With two sites now up and running, we hope to make much greater progress in obtaining combat injured subjects and their families over the next twelve months. However, this study's success is subject to the ability of qualified families who are willing to participate in research during a challenging time in their lives. In order to encourage participation we: 1) are attempting to increase awareness of the study at each of the three sites (i.e., we have created a recruitment poster for each site, a set of hand outs and study booklet to distribute to potentially interested subjects and professionals who interact with combat injured individuals); 2) have requested the change in inclusion criteria to increase the potential number of eligible subjects described above; and 3) have begun discussions with NNMC personnel to become part of the project when WRAMC migrates to the Bethesda site as part of the BRAC.

REFERENCES:

No references were cited in this annual report.

APPENDICES:

None supplied.