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TITLE: Development and Validation of a Theory Based Screening Process for Suicide Risk

PRINCIPAL INVESTIGATOR: Dr. Kari A. Stephen, Ph.D.

CONTRACTING ORGANIZATION: University of Washington

Seattle, WA 98195-0001

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14. ABSTRACT The ultimate objective of this study is to assist in increasing the capacity of military-based health services to accurately identify persons at risk for suicide and to render effective referral dispositions. To do so we will characterize and evaluate the ability of a proposed suicide screening instrument and associated clinical decision-making algorithm to accurately identify at-risk individuals and provide appropriate treatment recommendations. Furthermore we will evaluate key theoretical questions related to distinguishing who is at most risk for actual suicide. Dr. Kari Stephens became the University of Washington (UW) PI of record in August 2013 when Dr. Steven Vannoy, the former PI, accepted a faculty position at the University of Massachusetts - Boston. Dr. Vannoy became a co-investigator and remained the operational PI on the study. Recruitment operations continued at both Ft. Hood and JBLM until an Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO) involving data collection at JBLM halted recruitment at that site in August 2013. HRPO was notified and all documentation and corrective actions were reviewed and found to be in compliance with Federal, DOD and US Army human subjects protection requirements. Recruitment operations continue at Ft. Hood with personnel from the University of Texas Health Sciences Center at San Antonio (UTHSCSA) collecting data for UW. As of June 2014 a new measure added to the existing research questionnaire with the hope of improving the sensitivity of identifying at-risk individuals. Currently we have consented 687 subjects at JBLM, 511 at Ft. Hood, for a total of 1198 subjects. Due to various factors that have delayed our progress, the data collection and analyses phase of our study could not be completed by our original contract end date. We have requested and received a second one-year no-cost extension to complete the study in 2015. 15. SUBJECT TERMS Suicide risk, military, Army, screening, interpersonal theory of suicide, decision-makin											
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1. INTRODUCTION

The ultimate objective of this study is to assist in increasing the capacity of military-based health services to accurately identify persons at risk for suicide and to render effective referral dispositions. To do so we will characterize and evaluate the ability of a proposed suicide screening instrument and associated clinical decision-making algorithm to accurately identify at-risk individuals and provide appropriate treatment recommendations. Furthermore we will evaluate key theoretical questions related to distinguishing who is at most risk for actual suicide.

2. KEYWORDS

Suicide risk, military, Army, screening, interpersonal theory of suicide, decision-making algorithm

3. OVERALL PROJECT SUMMARY

Accomplishing tasks in the time frame proposed in our original timeline has been challenging primarily due to the lower number of soldiers available to consent than previously anticipated at both JBLM and at Ft. Hood, the PDHRA scheduling changes due to sequestration-required furloughs at JBLM, and the unexpected cessation of access to soldiers at JBLM as an outcome of an unanticipated problem involving risks to subjects or others (UPIRTSO).

A. Project Sites

Specific site status is described below:

JBLM

Data collection, which began in September 2012, continued through August 2013. The number of consented subjects was lower than anticipated in 2013 due to lower volumes of potential subjects being processed at the PDHRA clinic, and to the PDHRA Chief's decision to deny further recruitment after the occurrence of an UPIRTSO reported in August 2013.

Fort Hood

Data collection, which began May 2013, is continuing at Ft. Hood. We have continued our relationship with the STRONG STAR/UTHSCSA staff who are conducting our study at the SRP Center.

B. Human Subjects Approvals

In August 2013, Kari A. Stephens, Ph.D., Assistant Professor in the University of Washington's Department of Psychiatry and Behavioral Sciences was approved as the UW PI for this study as Dr. Steven Vannoy, the original PI on this study, accepted a faculty appointment at the University of Massachusetts – Boston. Dr. Vannoy remains the day-to-day operational PI and co-investigator for the study.

JBLM

On August 22, 2013, the convened UW Institutional Review Board (IRB) determined the unanticipated problem event was an UPIRTSO and requested that the investigators contact all personnel involved to inform them of the data loss and risk of possible identity theft. The UW IRB also deferred additional review and action to JBLM Command Staff. The JBLM Command Staff took immediate action to: 1) notify all potential persons impacted by the file loss; 2) set up a telephone hotline for 90 days to respond to incoming queries; 3) offer one year credit protection if wanted. The hotline period was completed 13 December 2013 with 11 persons responding, 4 persons enrolled in the credit monitoring service, and no complaints. On 5 December 2013, the UW IRB concurred with corrective actions to date. On 10 March 2014 and 1 May 2014, the ORP requested additional UW response and action regarding the corrective action plan; completed 28 May 2014.

Ft. Hood

On May 7, 2014, the UW IRB approved the addition of the Suicide Cognition Scale (SCS) as an additional item to the existing approved research questionnaire. This newer instrument was added to improve the quality of risk measurement. HRPO was informed of the requested change and agreed that the addition of the instrument did not potentially increase risk to subjects and therefore did not require HRPO approval. New questionnaire booklets were printed and administration of the augmented questionnaire began in June 2014.

C. Recruitment, consent & administration of initial screener and supplemental questionnaires

JBLM

The JBLM site has been closed to further recruitment for this study. A total of 687 subjects were consented between September 2012 and August 2013.

Ft. Hood

Our subcontracted research team, headed by Dr. Elisa Borah, from STRONG STAR/UTHSCSA began recruiting soldiers in May 2013. To date, 511 soldiers have been recruited for our study. Recruitment dates are contingent on deployment schedules; however, we are expecting that several thousand soldiers will be processed through the SRP center over the course of this summer and early fall 2014. We have consistently had a participation rate of 30% for this study at Ft. Hood. We seek to recruit another 400 subjects October 2014.

D. Data Analyses

We have begun this process on our preliminary data to accelerate final analytic procedures when we have the complete data set. We are approximately 50% complete in terms of code writing for planned analyses. We expect to be able to complete final data analyses by the spring of 2015.

E. Report writing and dissemination

We will complete these tasks once the analytic procedures are complete; although some manuscript writing will begin prior to the final data collection as our preliminary results are important and should not be delayed until all data have been collected. This is with particular respect to our data that confirms soldiers under report suicide ideation and that while they say that they would inform loved ones about suicidal thoughts, over 50% of soldiers who endorse ideation have not told anyone about it.

4. KEY RESEARCH ACCOMPLISHMENTS

To be determined after the Data Collection and Data Analysis phases are complete.

5. CONCLUSION

As we near completion of the data collection phase we are prepared to begin the data analysis and report writing tasks and are confident that we will be able to complete these tasks on time. The preliminary screening of the data indicates that we will be able to address the main goals of this study.

6. PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS

Initial data analyses and presentations at the American Association of Suicidology annual meeting, Los Angeles, CA 2014.

7. INVENTIONS, PATENTS AND LICENSES

Nothing to report.

8. REPORTABLE OUTCOMES

Nothing to report.

9. OTHER ACHIEVEMENTS

Nothing to report

REFERENCES

10. **APPENDICES**