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14. ABSTRACT In Project 1, we are adapting and empirically evaluating a safety plan intervention targeted at suicidal military service members receiving care at the Walter Reed National Military Medical Center. Outcomes include suicide ideation, suicide-related coping, and attitudes toward help seeking at discharge, 1-month, and 6-months post discharge. As of 9/24/2011, we have enrolled 6 participants in the study, all of whom are still active in the study. In Project 2, we are examining the effectiveness of a comprehensive intervention including the safety plan intervention and follow-up care, for veterans at high suicide risk at VA Emergency Departments (ED). Outcomes include suicide attempts, suicide ideation, and suicide-related coping at 1, 3, and 6 months following the index ED visit, as well as attendance at an outpatient mental health or substance abuse treatment appointment within 30 days post index ED visit. As of 9/24/2011, we have enrolled 96 participants across sites and 53 of these participants are still active in the study.					
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Introduction

The Army Suicide Event Reporting (ASER) and the Total Army Injury and Health Outcomes Database (TAIHOD) systems have indicated increasing rates of suicide among Active Army, Guard, and Reserve units over the last several years. Additionally, research has indicated that veterans are more than twice as likely to kill themselves as compared to the general population. There are limited evidence-based suicide prevention interventions that have been developed for military personnel and veterans who are experiencing suicide ideation or who have made a suicide attempt. The objective of the research described in this annual report is to adapt and evaluate a brief, readily accessible, and personalized intervention, safety planning, that aims to reduce suicide risk in military and veteran populations in three ways by: (1) evaluating suicide risk using a structured assessment measure; (2) enhancing suicide-related coping strategies; and (3) increasing acceptability and initiation of appropriate mental health and substance use treatments. This research is unique in that the intervention, safety planning, is being evaluated in both military and VA settings, with the aim of disseminating related educational materials to both military and VA patients and providers. The specific aims are to evaluate the efficacy of the safety planning intervention on suicide ideation, suicide-related coping, and attitudes toward help seeking for hospitalized military personnel at *high risk* for suicide and to evaluate the effectiveness of the safety planning intervention on suicide attempts, suicide ideation, attendance of outpatient mental health and substance abuse interventions, and suicide-related coping for veterans at high suicide risk in emergency department (ED) settings. Two separate, but related projects are being conducted to compare the study intervention with enhanced usual care conditions on suicide-related outcomes. In *Project 1*, the safety planning intervention has been adapted for military service members who are at high risk for suicide. A randomized controlled trial is being conducted to determine the efficacy of the safety planning intervention for hospitalized military personnel at the Walter Reed National Military Medical Center (formerly Walter Reed Army Medical Center). Outcomes include suicide ideation, suicide-related coping, and attitudes toward help seeking at discharge, 1-month, and 6-months post discharge. In *Project 2*, a quasi-experimental design is being used to examine the effectiveness of a comprehensive intervention including the safety plan intervention and follow-up care, for veterans at *high risk* for suicide at VA ED. Outcomes include suicide attempts, suicide ideation, and suicide-related coping at 1, 3, and 6 months following the index ED visit as well as attendance at an outpatient mental health or substance abuse treatment appointment within 30 days post the index ED visit. If the safety plan intervention is determined to be effective, then this intervention may be widely and quickly disseminated in the DoD and VA settings through publications and presentations using a variety of multi-media platforms. The ultimate goal of the safety plan dissemination initiative is to provide clinicians and other professionals who work with high risk military service members and veterans with a brief, easily administered intervention that is designed to mitigate suicide risk.

Body

During Year 2 of this project, extensive work has been conducted to secure approvals from all the institutional regulatory boards (IRBs) that have oversight on the implementation of both Project 1 (SAFEMIL) and Project 2 (SAFEVET). Recruitment of participants has now begun for both projects. The study PIs have been meeting once or at times twice weekly to discuss study objectives, methodology, timeline, and individual responsibilities. Discussions are documented in weekly *Meeting Minutes*. The first quarter focused heavily on the preparation and submission of IRB and regulatory-related materials as well as required study amendments. In December 2010, our request to USAMRMC for supplemental funds to hire an IRB Coordinator and half-time research assistant was approved. The financial arrangements for the study are handled by the Henry Jackson Foundation (HJF) and the corresponding PI grant representatives. HJF in collaboration with individual PI institutions has finalized setup of sub-award financial agreements for Year 2 and is currently drafting agreements for Year 3 (pending approvals). The second and third quarter continued to focus on the preparation and submission of IRB regulatory-related materials as well as required amendments across study sites. During these two quarters participant enrollment began at all four SAFEVET treatment sites. Study PIs disseminated their preliminary findings to the public during the Annual DoD/VA Suicide Prevention Conference that took place in Boston, MA on March 13-17, 2011. During the last quarter, participant enrollment has continued to be a focus and has also initiated for SAFEMIL. We have continued to work on obtaining final IRB and regulatory-related approvals for the remaining SAFEVET study control sites. A detailed summary of the progress for each project is detailed below.

Project 1 (SAFEMIL)

For Project 1, we have obtained approvals from the IRBs at the Walter Reed Army Medical Center (WRAMC)¹, the Uniformed Services University of the Health Sciences (USUHS), and the USAMRMC Office of Research, Human Research Protections Office (HRPO). The IRB protocol for SAFEMIL was approved by the WRAMC IRB on 12/14/2010, by the USUHS IRB on 8/3/2011, and by the HRPO IRB on 7/19/2011. Patient recruitment for SAFEMIL began on August 9, 2011, which was shortly after the WRAMC began its Base Reassignment and Closure (BRAC) transition from its Washington, DC location to its new campus at the National Navy Medical Center (NNMC) in Bethesda, MD. As of September 15, 2011, the Walter Reed National Military Medical Center (WRNMMC) became the official name of the combined military medical centers that represents the merger between WRAMC and NNMC.

As of Sept 24, 2011, we have enrolled 6 participants into the SAFEMIL study and all 6 participants are currently active in the study. The initial recruitment numbers for SAFEMIL have been lower than previously anticipated (initial estimates were 3 participants enrolled per week) due to the temporary difficulties created by the aforementioned BRAC transition. Algorithms for admitting inpatient psychiatric patients to WRAMC and subsequently WRNMMC were altered immediately prior to and after the BRAC transition to ease the burden on patients and providers during the transition. For three weeks near the end of July, area physicians were referring inpatient psychiatric admissions to other military hospitals in the area such as the hospital at Fort Belvoir. Towards the end of August, patients designated for admission at WRAMC were instead routed to NNMC and additional patients were still being re-routed to other military hospitals in the area. Additionally, WRAMC inpatient hospital staff members were split between both WRAMC and NNMC at that time. Census numbers for the inpatient psychiatric unit at WRAMC dropped from an average of 20 patients per day in May through June of 2011 to an average of 10 patients per day from August throughout most of

Please note that WRAMC underwent a Base Reassignment and Closure (BRAC) transition in September of 2011. For the purposes of this document, all references to WRAMC prior to September 15, 2011 are listed as Walter Reed Army Medical Center (WRAMC), which was located in Washington, DC. All references to Walter Reed on and after September 15, 2011 are listed as Walter Reed National Military Medical Center (WRNMMC), which is currently located in Bethesda, MD. The WRNMMC IRB established a policy such that WRNMMC IRB approval obtained from the WRAMC was automatically provided to all IRB protocols that had obtained IRB approval from the WRAMC IRB prior to the BRAC transition.

September of 2011. As of September 24, 2011, the WRNMMC inpatient psychiatric unit was continuing to operate at a limited capacity (only 16 of 24 possible beds were available for admissions). The WRNMMC inpatient psychiatric unit began operating at full capacity (24 beds available) in the first week of October 2011 for the first time since the beginning of Walter Reed's BRAC transition. It is anticipated that this increase in capacity will enable algorithms for admitting psychiatric inpatients to WRNMMC to return to what they were in May-June 2011 prior to the start of the BRAC transition. Consequently, we expect the daily census on the unit, in addition to SAFEMIL enrollment numbers, to increase in the upcoming months.

The SAFEMIL project team at USUHS has been meeting at least once weekly to discuss study objectives, methodology, timelines, and individual responsibilities. Discussions are documented in weekly *Meeting Minutes*. The fourth quarter focused heavily on designing and setting up a functional database, organizing and revising assessment forms to be more inclusive of the military population being served, and revising our regulatory materials per recommendations of the new WRNMMC IRB (formerly the WRAMC IRB). The WRNMMC IRB has given us permission to continue participant enrollment while these revisions are being made. We have also been working to finalize our assessment and follow-up procedural guideline as the new structure of the WRNMMC unit has made it necessary for us to revise these documents. All the aforementioned revisions and changes are being documented in an amendment memo that we plan to submit to the WRNMMC IRB in the next quarter.

The financial arrangements for the study were handled by the Henry Jackson Foundation (HJF) and the corresponding PI grant representatives. HJF in collaboration with individual PI institutions finalized setup of sub-award financial agreements for Year 2 and is currently drafting agreements for Year 3 (pending approvals).

Project 2 (SAFEVET)

For Project 2, we have obtained IRB approvals from the individual VA IRBs and the Chesapeake IRB, which is serving as the external IRB for the Henry Jackson Foundation, for all 9 of the VA Medical Centers (VAMC) that are serving as the study sites. Eight of the 9 study sites have also obtained approval from the HRPO IRB. The IRB protocol for the San Diego VAMC, a study control site, has not yet been approved by the HRPO IRB but is currently under review. Appendix A summarizes the information regarding when regulatory approvals were obtained for each study site.

All four of the SAFEVET treatment sites (Denver VAMC, Manhattan VAMC, Milwaukee VAMC, & Philadelphia VAMC) have begun participant recruitment at their respective sites. As of September 24, 2011, 96 participants had been enrolled into the SAFEVET study across all four sites and 53 participants were still active in the study. Appendix B summarizes the study site-specific enrollment data.

Key Research Accomplishments

For the 2nd year reporting period, here is a listing of all activities associated with SAFEMIL and SAFEVET.

Section I – SAFEMIL Progress

Safety Planning for Military (SAFE-MIL) - Walter Reed National Military Medical Center

1. Clarified Institutional Review Board Processes

The PIs and SAFEMIL project team members participated in face-to-face, phone, and/or email communication to determine the most efficient manner in submitting and gaining regulatory approvals for the conduct of the study. Although we obtained IRB approval from the WRAMC IRB prior to the Walter Reed's aforementioned BRAC transition, we had to re-clarify the IRB processes that were being utilized by the new WRNMMC after the BRAC transition. This included establishing/re-establishing contacts within the WRNMMC IRB and re-clarifying the processes for amendment submissions, adverse event reporting, and the language to include study protocols and consenting documents. Continued close communication with the WRNMMC IRB remains necessary as changes in the regulatory procedures being recommended by the WRNMMC IRB continue to be made.

2. Clarified Role of USUHS in the Regulatory Review Process

The study PI, Dr. Holloway, met with the USUHS IRB Coordinator and the Vice President of Research in order to clarify the role of USUHS in the regulatory process. An agreement was made that USUHS would review the SAFEMIL protocol and defer to their approval to the WRAMC IRB, and subsequently the WRNMMC IRB. The USUHS IRB also decided that they would not require a review of the SAFEVET protocol since studies associated with SAFEVET are already being reviewed by the VA IRB, the Chesapeake IRB, and the HRPO IRB.

The aforementioned decisions were documented in an email sent by Ms. Maggie Pickerel, the Director of the USUHS IRB, on 10/29/2010. This email reads as follows:

“A few weeks ago, Dr. Levine and I met with Dr. Holloway regarding IRB review of her above project. A decision was made that the USU IRB will conduct a secondary review of Dr. Holloway's WRAMC protocol. However, the protocols that are being conducted by non USU staff at the VA hospitals have been reviewed by Chesapeake IRB and several have already received a secondary approval by HRPO. Therefore, the USU's Human Research Protections Program/IRB will not be conducting a secondary review of these protocols. That being said, HJF will need to provide Bonnie Van Veldhuizen, Office of Sponsored Programs, VPR with copies of the approval documents, approved protocols, with all attachments (e.g. consent documents, advertisements, data collection sheets, etc.) for her files.”

3. Submitted Interim Cooperative Letter to WRAMC & Gained Approval of the Cooperative Research and Development Agreement (CRADA) on 11/18/2010

The CRADA document is a financial agreement between the HJF and WRAMC. We obtained approval of the study CRADA on 11/18/2010 after much collaboration with Mr. Steven Ross, the Grants Manager at WRAMC and now WRNMMC.

4. Obtained Approved Impact Statement from the Records Office at WRAMC

To gain access to patient electronic records, we submitted an Impact Statement for review by the Chief of Patient Records at WRAMC. Formal approval for this Impact Statement was obtained on 12/6/2010.

5. Obtained Letter of Support and Approval from the Armed Forces Health Surveillance Center (AFHSC) to Access the Defense Medical Surveillance System Database for Our Study Patients on 12/9/2010

We obtained permission from the Armed Force Health Surveillance Center (AFHSC) on 12/9/2010 to access the medical records of military personnel enrolled in our study via the military's population-based healthcare database known as the Defense Medical Surveillance System (DMSS; Rubertone & Brundage, 2002). Permission from participants to access their medical records is obtained via the study consent form, which includes a request to obtain information from the medical records of participants for 12 months prior to hospitalization and 12 months post hospitalization. The DMSS contains comprehensive population-based military health data starting from 1997 which includes the post deployment health assessment information. At a minimum, we expect to obtain an electronic record for all hospitalizations and ambulatory visits which will include date of visit, clinic type, and diagnoses coded using the ICD-9-CM but other information may be accessed as well for exploratory analyses.

6. Met with WRAMC Inpatient Psychiatry Chief and Assistant Chief on 10/15/2010

Dr. Holloway, the study PI, and several of the study research personnel met with LTC Geoffrey Grammer, Chief of WRAMC Inpatient Psychiatry, and Dr. Jennifer Weaver, Assistant Chief of WRAMC Inpatient Psychiatry, about study implementation related issues in mid October 2010. The objectives set out for the meeting were the following: (1) to provide an overview of the study's aims and methods, (2) to learn about the current inpatient treatment milieu (e.g., meal times, space, concurrent treatment), (3) to discuss implementation related issues so that collaborative decisions about best practices for implementation could be made, and (4) to foster a healthy collaborative relationship with inpatient staff and to address any questions and/or concerns they may have. The meeting was extremely collegial and our group was warmly welcomed to the unit. We discussed and problem-solved several implementation related issues. Based on recommendations from this meeting we developed an informational study handout to give to inpatient providers to clarify the study inclusion/exclusion criteria and to provide contact information of research staff to aid them in making patient referrals to the study. It is important to note that LTC Geoffrey Grammer continues to serve as the Chief of Inpatient Psychiatry at WRNMMC.

7. Began to Maintain a Presence at the Inpatient Unit of the WRAMC

In February 2011, the USUHS research personnel working on the SAFEMIL project began to have a regular presence at the WRAMC inpatient psychiatric unit from which our study participants are being recruited. Credentialed psychology personnel began attending morning reports on the inpatient psychiatric unit at this time, began developing a working relationship with the inpatient staff and leadership, started tracking patient admission data (i.e., census numbers, reasons for admission, etc.), and setup the necessary infrastructure for the conduct of our study. Our research staff continued to attend morning report at WRAMC throughout Walter Reed's BRAC transition until new patients were no longer being admitted there, at which time staff began attending morning report at the new WRNMMC location. Close work between the SAFEMIL staff and the staff on the inpatient psychiatric unit has helped to ensure that the transition caused no problems for our study plans. We have continued to meet regularly with LTC Geoffrey Grammer, the Inpatient Psychiatry Chief at WRNMMC, to stay abreast of the frequent changes on the inpatient psychiatric unit (i.e., changes to programming hours, visiting hours, turnover of residents, etc.) that have been occurring before, during, and after the BRAC transition.

8. Prepared IRB Documents for Submission to the WRNMMC

SAFEMIL research staff completed/collected the various required IRB documents for submission to the WRNMMC and USUHS IRB Boards. A list of these IRB documents is provided below:

- DMRN Research Project Cover Sheet
- Protocol
- Informed Consent/HIPAA

- Human Subjects Protection
- CITI course training certificates for Principal Investigator, Associate Investigators, Collaborating Personnel, and all other SAFEMIL Project Team Members.
- Curriculum Vitae for Principal Investigator, Associate Investigators and Medical Monitor, dated within 2 years
- Conflict of Interest Statement for Principal Investigator, Associate Investigators, Medical Monitor, and all USUHS Staff Members
- Consent form with HIPPA Authorization
- Impact statements
- Statements of Work

9. Obtained WRAMC and USUHS IRB Approval for Study and Requested Approval from HRPO

Approved WRAMC Human Use Committee study documents were submitted directly by Ms. Denise Neath, the WRAMC IRB Coordinator, to Ms. Karen Eaton at HRPO on 4/5/2011. On 4/20/2011, we received the HRPO's review of the research protocol and supportive documents and a listing of requested revisions based on an administrative review. We provided all requested documents/revisions to the HRPO on 5/10/2011. On 5/20/2011 we submitted an amendment packet to the WRAMC IRB to reflect all the requested changes from the HRPO and several minor revisions to the study protocol. On 6/15/2011 June 15, 2011, these documents were forwarded for administrative review by the WRAMC IRB. Ms. Denise Neath has been in frequent communication with our team and approval from the WRAMC IRB was received 7/14/2011. USUHS IRB granted approval on 8/3/2011. Subject recruitment for the SAFEMIL study began immediately after obtaining this final USUHS IRB approval.

10. Hired Qualified Study Personnel for the WRAMC Implementation of SAFE MIL

Dr. Holloway gained approval from HJF to advertise for several positions funded by the study. Applications were reviewed, candidates were interviewed, and appropriate hiring decisions were made in early 2011.

11. Conducted Monthly SAFEMIL/SAFEVET Rater's Call

A monthly call has been set up to for all SAFEMIL and SAFEVET assessors for the purpose of providing ongoing training and consultation in study assessment procedures to ensure standardization of the delivery and scoring of all study assessment measures. This monthly call, which all SAFEMIL and SAFEVET assessors are required to attend, is organized and supervised by Dr. Barbara Stanley from Columbia University.

12. Developed Motivation for Treatment Measure and the Brief Intervention Surveys

The *Motivation for Treatment Measure* and *Brief Intervention Surveys* were developed in order to allow study participants to provide their unique perspective about potential challenges associated with engaging in mental health care and to solicit feedback about the SAFEMIL study intervention.

13. Training of Providers

To date, Dr. John Dennis has provided a half-day workshop on the Safety Planning intervention to educate the study providers on the details of the intervention to be offered to SAFEMIL patients. On November 9, 2011, Dr. Gregory Brown from University of Pennsylvania is scheduled to provide a 2nd half-day workshop on the Safety Planning intervention. During this session, we plan to listen to several Safety Planning sessions and provide feedback to the providers.

Training seminars for study providers have been provided on an ongoing basis and have consisted of didactic training about the epidemiology, etiology, treatment and management of suicidal thoughts and behavior, and principles of clinical assessment. In addition, specific training has been provided for each

research instrument. A schedule of supervision, observation, and debriefing was implemented to ensure adherence, fidelity and competency. Trainings in study assessments have involved role play sessions that were audio-taped and reviewed by Dr. Barbara Stanley and associates at Columbia University. All study assessors have completed training and will continue to attend monthly SAFEMIL/SAFEVET Rater's calls with Dr. Barbara Stanley for the purposes of assessment consultation and supervision.

14. Finalized the SAFEMIL Master Database

A comprehensive database was developed and finalized. It is being utilized for the following functions: (1) recruitment, screening, and enrollments reports, (2) assessment protocol instructions and detailed instructions for administering the assessment measures, (3) collection of data from assessment interviews, (4) scheduling and tracking of assessment appointments and contact information, (5) tracking and reporting of adverse events, and (6) information to facilitate risk management. A great benefit of this database is that it ensures that all study assessment measures are being administered, scored, and interpreted in a standardized way.

15. Setup Computer Access/VPN

Our credentialed providers have obtained VPN access to the WRAMC inpatient medical records of participants on several laboratory laptop computers; however, given Walter Reed's BRAC transition, WRNMMC regulations have required our credentialed providers to undergo an additional lengthy security clearance process to obtain VPN access to the WRNMMC inpatient psychiatric medical records. All credentialed providers at WRAMC completed the WRNMMC security clearance application in early September 2011 and have been working closely with WRNMMC to ensure that our applications are processed without delay.

16. Finalized Treatment Guide for Safety Plan Intervention

Drs. Barbara Stanley, Greg Brown, and Marjan Holloway presented the details of the Safety Planning intervention during the Frederick, MD meeting held during the third quarter. The concepts reviewed in this meeting were summarized in an initial draft of the treatment guide and have since been refined and finalized in order to meet the specific and unique needs of military personnel being hospitalized at WRNMMC.

17. Finalized SAFEMIL Assessments, Assessment Guides, and Protocol

The SAFEMIL assessment battery was finalized following multiple meetings between the study PI's, project team, and database manager. Several assessment measures have been slightly modified in order to remain consistent with the US Census Data Reporting and to be more inclusive of the military population being served. The assessment guides have also been finalized. Minor revisions have been made to the study protocol and consent documents per the request from the WRNMMC IRB. An amendment packet is currently being prepared to document all of the aforementioned revisions. This amendment will be submitted to the WRNMMC IRB in the next quarter.

18. Changes to the Certificate of Confidentiality

Per recommendations from Ms. Olga Boikess and Mr. Brent Loomis, the Certificate of Confidentiality (CoC) Coordinators at NIMH, we have made minor changes to the language in our study consent form regarding our description of the circumstances in which the study CoC could and could not be used. More specifically, we have clarified that the CoC cannot be used to prevent requests from military command to obtain information about study participants. Our revised consent form will be submitted in the previously mentioned amendment packet that we plan to submit to the WRNMMC IRB in the next quarter. We have obtained permission from Ms. Boikess and Mr. Loomis to continue using our current consent form until the revised consent form is approved by the WRNMMC IRB.

19. Attended Annual DoD/VA Suicide Prevention Conference March 13-17, 2011 in Boston, MA

All PIs attended and presented at the DoD/VA Annual Suicide Prevention conference held in Boston, MA on March 13-17, 2011. The purpose of the conference was to offer an opportunity to disseminate practical tools and innovative research in the area of suicidology. Four tracks were offered to focus on practical applications and innovations: (1) clinical; (2) multi-disciplinary; (3) family/peer-to-peer; and (4) research. The target audiences for the conference included service members, veterans, families, caregivers (e.g. social workers and counselors), members of academia, researchers, physicians, clinicians, federals and non-federal agencies. A list of presentations made by the study PIs during this conference is provided in this report (p. 16 – Reportable Outcomes).

Section II – SAFEVET Progress

Safety Planning for Veterans (SAFEVET) – VA Emergency Departments

1. Obtained Regulatory Approvals from the Following VA IRBs:

- Portland VAMC
- Milwaukee VAMC
- Bronx VAMC
- Canandaigua VAMC (Syracuse IRB)
- San Diego VAMC
- Long Beach VAMC

2. Obtained Regulatory Approval from the Chesapeake IRB for the Following VA Sites:

- Portland VAMC
- Milwaukee VAMC
- Bronx VAMC
- Canandaigua VAMC
- San Diego VAMC
- Long Beach VAMC

3. Obtained Regulatory Approval from HRPO for the Following VA Sites:

- Portland VAMC
- Milwaukee VAMC
- Bronx VAMC
- Canandaigua VAMC
- Long Beach VAMC

4. Obtained Continuing Review Approvals from the Following VA IRBs:

- Denver VAMC
- Manhattan VAMC
- Philadelphia VAMC

5. Obtained Continuing Review Approval from the Chesapeake IRB for the Following VA Sites:

- Denver VAMC
- Manhattan VAMC
- Philadelphia VAMC

6. Obtained Continuing Review Approval from HRPO for the Following VA Sites

- Denver VAMC
- Manhattan VAMC
- Philadelphia VAMC

7. Enrolled 28 Participants at Manhattan site

In Manhattan, data collection started in December 2010, and 28 Veterans have been enrolled to date. Recruitment and follow-up continues at this site. Five participants have completed the study.

8. Enrolled 29 Participants at Denver site

In Denver, recruitment and data collection was initiated in December 2010. As of the end of year 2, Denver staff has recruited 29 participants. Five participants have completed the study. Recruitment and follow-up continues at this site. At the Long Beach site, regulatory approval has been obtained and hiring of staff has commenced.

9. Enrolled 38 Participants at Philadelphia site

In Philadelphia, recruitment and data collection began in December 2010 and 38 participants have been enrolled to date. Three participants have completed the study. Recruitment and follow-up continues at this site.

10. Enrolled 1 Participant at Milwaukee site

Recruitment and data collection for the Milwaukee VA site began and the first participant was enrolled on 9/20/2011. Recruitment and follow-up continues at this site.

11. Assisted Control Sites with Regulatory Documentation

The Denver VA worked closely with each of the control sites on their IRB submission documents to ensure protocol version control and continuity between the sites. In addition, each SAFEVET Assessment site assisted their respective paired Control site with regulatory documentation.

12. Coordinated with Long Beach Control Site – Denver VA

The Denver site created a shared folder with the Long Beach site behind the VA firewall to facilitate the secure sharing of data. Denver assisted Long Beach in hiring decisions and is planning to facilitate the initiation of recruitment as soon as the Long Beach staff is hired.

13. Coordinated with Portland SAFEVET Site and San Diego Control Site – Canandaigua VA

The Canandaigua VA continues to be primary liaison to the Portland, Oregon, VAMC active site, as well as the San Diego, CA, control site for SAFE VET. Portland IRB approval has been obtained, staff has been hired, and protocols for transfer of clinical information between Portland and Canandaigua have been developed. Portland is now prepared to recruit subjects. We continue to work with San Diego VAMC, and an IRB application has been submitted, has been approved locally

14. Coordinated with Bronx Control Site – Manhattan VA

The Manhattan site has developed protocols for transfer of clinical information between Bronx and Manhattan. The Bronx has obtained regulatory approval, the new assessor has been medically cleared and is awaiting CPRS access to begin data collection.

15. Coordinated with Milwaukee Control Site – Philadelphia VA

The Philadelphia site has developed protocols for transfer of clinical information between Milwaukee and Philadelphia. Milwaukee has obtained regulatory approval and has commenced recruitment for the study.

16. Completed, Tested, and Modified the Master Assessment Database

This de-identified and password-protected Microsoft Access database includes: (1) screening and enrollments reports, (2) assessment protocol instructions and detailed instructions for administering the assessment measures, (3) collection of data from assessment interviews, (4) scheduling and tracking of assessment appointments, (5) tracking and reporting of adverse events (customized for each recruitment site), and (6) information to facilitate risk management. Each assessment site has two customized databases – one for their SAFE-VET data and a second for their paired Control site’s data. The Philadelphia site was primarily responsible for the developing, testing, and training others on the SAFEVET Master Assessment Database.

17. Developed a Separate Study Database to Store Protected Health Information (PHI)

Each assessment site has two customized password-protected databases – one for their SAFE-VET PHI data and a second for their paired Control site’s PHI data.

18. Developed a Separate Screening and Enrollment Database

Each study site has a customized Excel database for their site’s screening and enrollment data. Associated weekly screening and enrollment report templates were created. Weekly de-identified enrollment reports are emailed to all study sites and are presented weekly on a phone conference of the PIs on the executive committee.

19. Trained Assessors on the Usage of the Master Assessment Database

Conference calls were held to train assessors at each assessment site in the use of the Master Assessment Database.

20. Conducted Rater Trainings and Provided Ongoing Consultation

Columbia University has taken responsibility for the evaluation of rater training tapes and gave verbal/written feedback to all assessors for the project. Columbia University maintains responsibility for training and evaluation of rater training tapes. Verbal and written feedback has been given to all assessors for the project. A monthly raters' meeting has been initiated and chaired by Dr. Stanley.

21. Trained Assessor at the Bronx and Manhattan VAMCs

We trained and credentialed a new rater for Manhattan and Bronx VAMCs as the first rater left the position in August 2011 to return to school. The new assessor is conducting the assessments for the Manhattan and Bronx VAs. The assessor was trained. She taped an interview to evaluate adherence and was given feedback. Data collection has continued at the Manhattan VA for the Safe Vet study. Data collection will begin at the Bronx VA as soon as the new assessor obtains access to CPRS.

22. Trained Assessor at the Denver and Long Beach VAMCs

The Denver site hired a new (second) assessor to assist with local assessments as well as the Long Beach assessments. She is currently being trained on the assessment battery. She was added to the protocol, listened to training tapes, observed assessments and completed a training tape to be reviewed at the Manhattan VA/Columbia site. Both Denver assessors also participate in monthly phone calls to facilitate communication and consistency across assessor sites.

23. Trained Assessor at the Canandaigua VAMC

Canandaigua study staff has been hired and trained to conduct follow-up telephone assessments of study participants enrolled at the Portland VAMC and San Diego VAMC. Assessors training tapes were recorded and sent for review at the Manhattan VA/Columbia site.

24. Trained Assessors at the Philadelphia VAMC

Two assessors were trained on all assessment measures and their research interviews were recorded and sent for review by the Manhattan VA/Columbia site. The assessors conduct assessments with participants enrolled at the Philadelphia VAMC and Milwaukee VAMC.

25. Hired IRB Coordinator

An IRB coordinator was hired to coordinate and track the submission and approvals of IRB applications and reports for all sites, track current IRB status and due dates for each site, maintain copies of all documents submitted to local IRBs, review, compile and email sites' IRB submissions to the study's contact at Henry Jackson Foundation for submission to Chesapeake IRB and HRPO, review IRB protocols for consistency with the master protocol, assist sites in setting up Regulatory Binders for the study, assist sites in reporting adverse events and notifying all sites of adverse events, and compile enrollment data and provide weekly enrollment reports to PIs.

26. Developed Adverse Events Notification Procedures

The Adverse Event Reporting protocol was developed, including an Adverse Event Notification Form, as a means to notify all sites of all AEs that occurs during the course of the study. Weekly adverse event reports were collected from all sites and AEs were discussed during a weekly PI conference call.

27. Developed Standard Operating Procedures and Submitted to Appropriate IRBs

We developed a Standard Operating Procedure (SOP) manual for the study and oversaw the submission of these SOPs to local IRBs.

28. Created Data Use Agreements

The Denver VA created a Data Use Agreement template for each site to utilize.

29. Finalized Study Risk Management Protocol & Adverse Event Reporting

An agreement for the provision of further assistance to SAFE VET Assessors who deemed a participant at risk was developed and signed. A warm transfer from the assessor to the VA National Suicide Prevention Hotline located in Canandaigua, New York, is provided.

30. Finalized the Protocol for Screening and Enrolling Study Participants

The protocol for screening and enrolling participants at each study site was finalized and distributed to each study site.

31. Completed Staff Key Informant Interviews and obtained approvals to conduct Veteran Key Informant Interviews

In April 2011, funds were allocated to conduct key informant interviews with both VA Staff and Veterans who participated in SAFE VET. During Q4, 2011, Barbara Stanley, Ph.D. and Greg Brown, Ph.D., along with staff at CUMC and University of Pennsylvania, developed and piloted two different sets of interview questions, submitted and received approval to conduct staff interviews at 5 SAFE VET demonstration sites, and received approval to conduct Veteran interviews at the Manhattan VAMC.

32. Completed Community Outreach Video Project

We completed the Community Outreach video project for use by Acute Services Coordinators as they educate community emergency departments in their vicinities about the SAFE VET project.

33. Disseminated Study-Related Information

Several of the PIs for this project attended the Advisory Board meeting and presented this project to the Canandaigua Center of Excellence Advisory Board meeting in April 2011. An overview of the background and methods of the project was presented as well as results on the acceptability and feasibility of the Safe Vet intervention being evaluated in this grant. SAFE VET preliminary findings were also presented at the Government Services Administration meeting in San Antonio, and the VA Mental Health Services Conference in Baltimore.

34. Obtained SAFE VET Monthly Reports

All SAFE VET intervention sites are submitting monthly reports regarding suicide-related variables in the VA EDs and follow-up information from the VA medical records. Activities of the Acute Services Coordinators are also provided in a monthly report.

Reportable Outcomes

Peer Reviewed Manuscripts

Dennis, J., Ghahramanlou-Holloway, M., Cox, D., & Brown, G. (2011). A guide for the assessment and treatment of suicidal patients with traumatic brain injuries. *Journal of Head Trauma Rehabilitation, 26*, 244-256.

Ghahramanlou-Holloway, M., Cox, D., Fritz, L., & George, B. (2011). An evidence informed guide for working with military women and veterans. *Professional Psychology: Research and Practice, 42*, 1-7.

Knox, K., Brown, G., Stanley, B., Currier, G., Brenner, L., & Ghahramanlou-Holloway, M. (in-press). An emergency department based brief intervention for Veterans at risk for suicide (SAFE VET). *American Journal of Public Health*.

Stanley, B. & Brown, G. K. (2011). Safety Planning Intervention: A Brief Intervention to Mitigate Suicide Risk, *Cognitive and Behavioral Practice*. doi:[10.1016/j.cbpra.2011.01.001](https://doi.org/10.1016/j.cbpra.2011.01.001)

Presentations

Brenner, L. & Kudler, H. (September 2011). Real World Solutions through Veteran-Centered Care: VISN 6 and VISN 19 MIRECC. VHA Improvement Forum: Bridging to Excellence in the 21st Century, Las Vegas, NV.

Currier, G. (March 2011). SAFE VET- Treating veterans at moderate risk of suicide in the emergency department. Government Services Symposium, San Antonio, TX.

Ghahramanlou-Holloway, M. (2011, March). *Evidence-Based Psychotherapy for Suicide Prevention: Strategies from the Civilian and Military Sectors*. Invited presentation given at the 2011 DoD/VA Annual Suicide Prevention Conference, Boston, MA.

Ghahramanlou-Holloway, M. & Knox, K. (2011, March). *Research on Suicide Prevention Interventions*. Invited presentation given at the 2011 DoD/VA Annual Suicide Prevention Conference, Boston, MA.

Knox, K., Brown, G., Brenner, L., Currier, G., & Stanley, B. (August, 2011). *SAFE VET: A Brief Intervention to Mitigate Suicide Risk in Acute Settings: Initial Findings*. VHA Mental Health Conference, Baltimore, MD.

Knox, K., Brown, G., Currier, G., & Stanley, B. (2011, March). *Brief Interventions to Mitigate Suicide Risk in Acute Settings: Initial Findings and Implications*. Invited presentation given at the 2011 DoD/VA Annual Suicide Prevention Conference, Boston, MA.

Conclusion

We expect to have preliminary study results to share in the next annual report (Year 3) for this study. Currently, there are no study findings on primary and secondary outcomes to report at the present time. However, tables documenting preliminary SAFEMIL and SAFEVET enrollment data and adverse event reporting are included in Appendices A through D.

For SAFEMIL, the second year has heavily focused on obtaining appropriate regulatory approvals, finalizing study measures, hiring and training study personnel, preparing the study assessment battery, communicating with sites about study setup, coordinating a systematic approach to adverse event reporting, and the creation of the study master database. Recruitment of SAFEMIL participants began in August 2011 and was concurrent with Walter Reed's BRAC transition from Washington, DC to Bethesda, MD. As of 9/24/2011, we have enrolled 6 participants in the study, all of whom are still active in the study. Initial recruitment has been lower than previously anticipated due to the challenges associated with this transition. Follow-up assessments for SAFEMIL participants will begin on September 29, 2011. We anticipate that our recruitment rate will increase in the next quarter as the inpatient psychiatric unit at WRNMMC has returned to full capacity as of the first week in October 2011. Given that no SAFEMIL study participants have completed their enrollment in the study, we have no significant data to report at this time.

Regarding the SAFEVET study, the second year was focused on patient recruitment and follow-up at the SAFEVET sites, obtaining appropriate regulatory approvals and hiring study personnel at Control sites and coordinating activities between Assessment sites and their paired Control sites. Recruitment of study participants began in December 2010 at three of the SAFEVET sites and in September 2011 at one of the Control sites. As of 9/24/2011, we have enrolled 96 participants across sites and 53 of these participants are still active in the study. We anticipate that recruitment at all other sites will commence soon.

This study represents the only combined efficacy and effectiveness trial addressing the needs of military personnel and veterans following a suicidal crisis. Given the magnitude of the public health problem presented by suicide-related ideation and behaviors in the military, there is a significant need for empirically supported treatments that directly address the needs of this at high-risk individuals.

References

None.

Appendices

Appendix A: IRB Related Progress for SAFEVET and SAFEMIL Projects

Appendix B: SAFEVET Enrollment Report and Adverse Event Log

Appendix C: SAFEMIL Enrollment Report and Adverse Event Log

Appendix D: SAFEVET and SAFEMIL Participants Lost to Follow-up

Appendix E: SAFEVET Conference Agenda, Boston, MA – March 14, 2011

APPENDIX A

IRB Related Progress for SAFEVET and SAFEMIL Projects (As of September 24, 2011)

IRB	Site #1 Bronx VAMC CONTROL	Site #2 Canandaigua VAMC ASSESSMENT SITE ¹	Site #3 San Diego VAMC CONTROL	Site #4 Denver VAMC SAFEVET	Site #5 Long Beach VAMC CONTROL
Site PI	Leo Sher	Glenn Currier Kerry Knox	Kathleen Kim	Lisa Brenner	Lawrence Albers
VA IRB	Approved 12/2/2010	Syracuse IRB Approved 1/3/2011	Approved 3/3/2011	Approved 5/7/2010 CR Approved: 3/11/11	Approved 6/9/2011
PI Institutional IRB	NA	NA	NA	NA	NA
Chesapeake IRB	Approved 5/25/2011	Approved 4/5/2011	Approved 7/6/2011	Approved 9/09/2010 CR Approved 6/1/2011	Approved 8/31/2011
HRPO	Approved 6/21/2011 HRPO A-15768.h	Approved 5/25/2011 HRPO A-15768.f	Under Review HRPO A-15768.i	Approved 9/14/2010 CR Approved: 9/2/11 HRPO A-15768.a	Approved 9/20/2011 HRPO A-15768.j
Other IRB	NA	NA	NA	NA	NA
RISK	No Greater than Minimal Risk	No Greater than Minimal Risk	No Greater than Minimal Risk	No Greater than Minimal Risk	No Greater than Minimal Risk
SAMPLE SIZE	N = 75 at BVAMC	N = 75 at CVAMC	N = 75 at SDVAMC	N = 75 at DVAMC	N = 75 at LBVAMC

¹ Assessment Center for San Diego and Portland VAMCs

IRB	Site #6 Manhattan VAMC SAFEVET	Site #7 Milwaukee VAMC CONTROL	Site #8 Philadelphia VAMC SAFEVET	Site #9 Portland VAMC SAFEVET	Site #10 WRAMC SAFEMIL
Site PI	Christie Jackson	Aruna Jha	Gregory Brown	Lauren Denneson	Marjan Holloway
VA IRB	Approved 5/3/2010 CR Approved 3/28/11	Approved 2/15/2011	Approved 5/12/2010 CR Approved: 3/16/11	Approved 11/3/2010 CR: Under Review	NA
PI Institutional IRB	NA	NA	NA	NA	USUHS (SAFEMIL ONLY) Approved 8/3/2011
Chesapeake IRB	Approved 6/17/2010 CR Approved 6/1/2011	Approved 4/5/2011	Approved 8/09/2010 CR Approved 6/1/2011	Approved 1/31/2011	NA
HRPO	Approved 9/24/2010 CR Approved: 9/2/11 HRPO A-15768.b	Approved 5/25/2011 HRPO A-15768.g	Approved 9/02/2010 CR Approved: 9/2/11 HRPO A-15768.c	Approved 2/28/2011 HRPO A-15768.d	Approved 7/19/2011 HRPO A-15768.e
Other IRB	NA	NA	NA	NA	WRAMC Approved 12/14/2010
RISK	No Greater than Minimal Risk	No Greater than Minimal Risk	No Greater than Minimal Risk	No Greater than Minimal Risk	Greater than Minimal Risk
SAMPLE SIZE	N = 75	N = 75	N = 75	N = 75	N = 186

CR = Continuing Review; CIC = Clinical Investigations Committee; HRPO = Human Research Protections Office; HUC = Human Use Committee; USUHS = Uniformed Services University of the Health Sciences; VAMC = Veterans Affairs Medical Center; WRAMC = Walter Reed Army Medical Center

APPENDIX B

SAFEVET Enrollment Report and Adverse Event Log (As of September 24, 2011)

	Assessed for Eligibility	Ineligible	Eligible but Refused Entry into Study	Eligible but not Enrolled – Other Reasons	Enrolled	Active	Completed Baseline Assessment	Completed 1-mo follow-up	Completed 3-month follow-up	Completed Study	Lost to Follow-up	# AEs
Total (all sites):	152	46	10	-	96	53	69	46	31	13	30	3
Bronx	-	-	-	-	-	-	-	-	-	-	-	-
Denver	39	7	3	-	29	19	25	17	13	5	5	1
Long Beach	-	-	-	-	-	-	-	-	-	-	-	-
Manhattan	52	21	3	-	28	14	18	11	10	5	9	1
Milwaukee	1	0	0	-	1	1	1	-	-	0	0	0
Philadelphia	60	18	4	-	38	19	25	18	8	3	16	1
Portland	-	-	-	-	-	-	-	-	-	-	-	-
San Diego	-	-	-	-	-	-	-	-	-	-	-	-

APPENDIX B continued
SAFEVET Adverse Events Log (As of September 24, 2011)

Site	Date of Event	Date of Discovery	Date reported to local IRB	Description	Expected / Unexpected	Related to Study
Manhattan	2/17/2011	2/18/2011	2/25/2011	Suicide Attempt	Expected	No
Philadelphia	7/13/2011	7/28/2011	7/29/2011	Hit by Train resulting in death	Unexpected	No
Denver	8/2/2011	8/5/2011	8/8/2011	Suicide Attempt resulting in death	Expected	No

APPENDIX C

SAFEMIL Enrollment Report and Adverse Event Log (As of September 24, 2011)

	Assessed for Eligibility	Ineligible	Eligible but Refused Entry into Study	Eligible but not Enrolled – Other Reasons	Enrolled	Active	Completed Baseline Assessment	Completed Discharge Assessment	Completed 1-month follow-up	Completed Study	Lost to Follow-up	# AEs
SAFEMIL	23	8	3	6	6	6	6	6	-	-	0	0

SAFEMIL Adverse Events Log (As of September 24, 2011)

No adverse events reported

APPENDIX D
SAFEVET and SAFEMIL Participants Lost to Follow-up (As of September 24, 2011)

SAFEVET Reasons for Participants Lost to Follow-up

30	Total # of subjects lost to follow-up
21	Withdrawn because did not complete baseline assessment within 7 day timeframe
3	Subjects withdrew because too busy to complete assessments
2	Subjects withdrew because no longer interested in participating
2	Subjects withdrew because no longer comfortable with study
2	Subjects deceased

SAFEMIL Reasons for Participants Lost to Follow-up (SAFEMIL)

No Subjects Lost to Follow-up

APPENDIX E

SAFEVET Conference Agenda March 14, 2011 (Boston, MA)

Time	Topic	Presenter
1:00 – 1:30pm	Welcome and Introductions	Executive Committee
1:30 – 2:00pm	Data Review	Executive Committee
2:00 – 2:15pm	MOMRP Study	Marjan Holloway
2:15 – 3:15pm	Site Update/Lessons Learned	Group
3:15 – 3:30pm	Break	
3:30 – 4:30pm	Finalize ASC Manual/ Follow-Up Call Review	Greg Brown/Barbara Stanley
4:30 – 5:30pm	Strategize Implications for Next Steps/ Community ED's	Glenn Currier/Lisa Brenner
5:30 – 6:00pm	Question and Answers	Executive Committee