

AWARD NUMBER: W81XWH-14-1-0005

TITLE: Intervening to Reduce Suicide Risk in Veterans with Substance Use Disorders

PRINCIPAL INVESTIGATOR: Mark Ilgen, Ph.D.

CONTRACTING ORGANIZATION: University of Michigan
ANN ARBOR, MI 48109

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14. ABSTRACT Reducing suicide risk among active duty soldiers and Veterans is a national priority. Because substance use disorders (SUDs) are key risk factors for both fatal and non-fatal suicidal behaviors, SUD treatment program staff are in frequent contact with high-risk individuals. However, no data exist on the efficacy of suicide-specific interventions conducted in SUD Treatment. The proposed research study addresses this gap by testing the efficacy of a targeted intervention designed to reduce suicide risk in Veterans treated for SUDs. The primary objective of this study is to evaluate the impact of a Cognitive Behavioral Therapy (CBT) intervention compared to a Supportive Psycho-education Control (SPC) condition on subsequent suicidal thoughts and behaviors in Veterans with SUDs. During this research period, project staff have been refining study materials and measures, hiring key project staff, and submitting applications to various regulatory boards for approval to prepare for subject recruitment.					
15. SUBJECT TERMS Suicide, Veterans, Substance Use Disorders					
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1. INTRODUCTION

The evaluation of strategies to reduce suicide among former members of the US armed forces is of high public health significance. Previous research has found that substance use disorders (SUDs) are key risk factors for both fatal and non-fatal suicidal behaviors. Because of this, SUD treatment program staff are in frequent contact with high-risk individuals. However, no data exist on the efficacy of suicide-specific interventions conducted in SUD treatment. Testing an intervention for use with suicidal Veterans seen in intensive outpatient SUD treatment programs within various Veteran Affairs Medical Centers (VAMCs) has the potential to significantly improve functioning and well-being, and decrease the substantial loss of life in Veterans with SUDs due to suicide. The overall purpose of this project is to adapt and evaluate the impact of a Cognitive Behavioral Therapy (CBT) intervention compared to a Supportive Psycho-education Control (SPC) intervention on subsequent suicidal thoughts and behaviors in Veterans with SUDs. The study has two primary components: (a) refining the intervention content for use in Veterans Health Administration (VHA) patients and (b) conducting a multisite randomized controlled trial (RCT) with 300 participants to examine the efficacy of this individual CBT intervention in reducing suicidal thoughts and behaviors in VHA patients receiving treatment for a SUD over a 2 year follow-up period.

2. KEYWORDS

Suicide, Suicidal Thoughts, Suicide Attempts, Substance Use Disorders, Alcohol Dependence, Drug Dependence, Addiction, Veterans, OEF/OIF

3. ACCOMPLISHMENTS

- *What are the major goals and objectives of the project?*

The proposed project is a fully-powered randomized controlled trial (RCT) of the CBT intervention versus the SPC intervention for 300 suicidal Veterans seen in SUD Intensive Outpatient treatment at various VHAs to examine changes in suicidal thoughts, non-fatal attempts, substance use and depression for two years post-intervention. The specific aims are to: (1) compare CBT and SPC in reducing the frequency and intensity of suicidal thoughts at 1-, 3-, 6-, 12-, 18-, and 24-months; and (2) compare CBT and SPC in decreasing the likelihood of suicide attempts at 1-, 3-, 6-, 12-, 18-, and 24-months. The secondary aims are to (1) compare the CBT condition to the SPC condition in the frequency of illicit drug use, alcohol use, nonmedical opioid medication misuse, self-efficacy and depressive symptoms at 1-, 3-, 6-, 12-, 18-, and 24-months; and (2) examine whether OEF/OIF status moderates the effect of treatment assignment (CBT vs. SPC) on post-treatment suicidal thoughts, behaviors and substance use.

As outlined in the SOW, the major goals for the first year of this project are primarily related to project start-up and include 1) hiring project staff, 2) refining the

intervention manuals, 3) creating study binders (i.e., regulatory, training), 4) refining risk management procedures, 5) modifying study measures for assessments, 6) obtaining Human Subjects (IRB) and Research and Development (R&D) approval, 7) obtaining a certificate of confidentiality, 8) training therapists and staff, 9) and assembling the Data Safety Monitoring Board.

- *What was accomplished under these goals?*

During this first year, our main objectives, activities, and accomplishments have focused on project start-up. This began with hiring study personnel, including the IRB coordinator and the study coordinators in the primary study sites, Ann Arbor, MI and Denver, CO. In March 2014, study members from Ann Arbor travelled to Colorado to meet with key study personnel, including the site PI. As a result of this meeting, modifications were made to the intervention and the protocols regarding the recruitment of individuals at each site. In addition, other key study issues were discussed including the management and sharing of data across sites, including where and how the data may be stored (shared network drives) and the creation of the computerized assessment tools and study databases. To facilitate study start-up across a multi-site study, we have developed a communication plan between the Michigan sites (Ann Arbor and Detroit) and the sites in Colorado (Denver and Colorado Springs), which includes regular correspondence via phone, internet, and e-mail. We also conduct monthly meetings of the Investigators at the Michigan site to discuss the status of the project. These meetings and correspondences have been focused on refining aspects of the study protocol, making key decisions about study design, and working to submit applications to the appropriate regulatory boards for approval. In May 2014, the study PI met with personnel from the DoD as part of a DoD sponsored meeting. We have also strengthened our ties with the Detroit VAMC and have a new collaborator there who will be key in ensuring successful recruitment and risk management in Detroit. We continue to work collaboratively with all project personnel across study sites to prepare for study recruitment and intervention implementation at each site, which will commence within the next reporting period. We also received approval in July 2014 to add an additional recruitment site (the Ann Arbor VAMC) to the project because many of the staff and investigators are located in Ann Arbor, Michigan. This will help to ease staff burden (reducing some travel to/from Ann Arbor to the Detroit VA) and would be beneficial in reaching our recruitment goals.

In addition, during this reporting period we have revised our project intervention manuals to include veteran specific materials with the help of our consultants who specialize in tailoring materials to Veterans,. We have also reviewed and revised our risk management procedures to ensure that we are providing appropriate resources for our participants in high-risk situations. Based on these and other modifications and refinements to our protocol, we submitted a draft of our proposal to the TATRC Regulatory Compliance Specialist (RCS) who provided us with feedback. Based on this feedback, we continued to review and revise our protocols and procedures to comply with suggestions provided by our RCS, and received subsequent approval to begin the submission process to our Institutional Review Boards (IRBs) in September 2014. We immediately began the process of submitting

our proposal to our local IRBs. Since then we have accomplished the following: we submitted an application to the University of Michigan IRBMED and received approval in December 2014; we submitted our application to the Ann Arbor VA HSR&D and IRB and have since received comments and feedback from the IRB and several additional VA committees and have resubmitted our application based on their feedback and contingencies; we have submitted our application to the Denver VAMC R&D committee (which must pre-approve all applications prior to IRB submission) and received approval to submit to the Colorado IRB in January 2015; finally, we have compiled our materials to submit to the Detroit VA R&D committee and the Wayne State IRB and will submit those for review within the next month. We are awaiting approval from the Detroit VA for some administrative components (related to staff effort) of our applications before they can be submitted.

Due to the length of the submissions to the IRBs and R&Ds and since we have not yet received approval from the Ann Arbor VA (which is the main study site), we have yet to submit our application for our Certificate of Confidentiality. We have also delayed in hiring of additional project staff including project therapists and research assistants until we are ready to start recruitment so that we can make full use of the effort of these members of the study team. We anticipate that we will begin the hiring process within the next month of the project, and the next reporting period will focus on hiring and training of research staff. We anticipate that we will be able to start recruitment early within the next reporting year at the study sites, which will only result in a slight delay from our timeline proposed in our SOW. Given the complex, complicated, and serious nature of the population being studied (suicidal Veterans in substance abuse treatment), we have spent the majority of this first reporting year focusing on developing protocols that will ensure the safety of our participants and careful adherence to all the policies and regulations of our study sites.

- *What opportunities for training and professional development did the project provide?*

Nothing to Report.

- *How were the results disseminated to communities of interest?*

Nothing to Report.

- *What do you plan to do during the next reporting period to accomplish the goals and the objectives?*

During the next reporting period, we plan to continue to accomplish several key tasks as we move towards starting recruitment for this project. Specifically, we will continue to hire project staff, including the project therapists and research assistants. We also plan to conduct extensive training of all project protocols and procedures with study staff. Project therapists who will be delivering our CBT and SPC interventions will participate in 2-day training workshops which will be co-facilitated by our project consultant (Dr. Gregory Brown). These trainings will focus on provided background for the manuals, a review of key skills necessary in

delivering the intervention, and opportunities to practice the material. These trainings will help ensure all project therapists received the same training and guidance before the start of the project. Similar training will be conducted with the research assistants at each study site. Since the population of study is particularly high risk, all study staff will receive extensive training in managing suicidal and homicidal crises during the next reporting period. We anticipate that this will be an ongoing training, where staff will continue to meet regularly throughout the study to process and refine the management of these issues. We also will focus on finalizing our internal study documents during the next reporting period, including the creation of project databases and information sheets that will be used to track participants throughout the study. In addition, during the next reporting period we plan to receive approval from all IRBs and submit our project to HRPO for final approval. Once approval has been received, we will begin subject recruitment, enrollment, and intervention delivery at each of the study locations. We believe that we have created a solid foundation for this project through our collaboration and effort during this first reporting period, and are confident that we will be able to achieve our goals as outlined in our SOW to begin subject recruitment and enrollment within the next reporting period.

4. IMPACT

Nothing to Report.

5. CHANGES/PROBLEMS

- *Changes in approach and reasons for change*

We made several changes to the study during this reporting period. We initially planned to utilize a three-stage approach that included conducting pilot groups to determine feasibility, acceptability, and fidelity of the intervention. However, because of concerns about the project timeline, we revised this portion of the intervention development plan. We estimated that piloting our intervention could delay the main portion of the project by up to 6-9 months due to the time needed to obtain IRB approval from all study sites for both the pilot and final version of our intervention protocol. Because we had previously utilized similar interventions for Veterans with chronic pain and/or brain injury, as well as a similar intervention in a residential SUD treatment center, we reduced participant and staff burden by dropping the process piloting the intervention with Veterans. Instead, we sought input on the intervention from content experts and current colleagues with expertise in working with active duty military personnel and Veterans. This allowed us to refine the content of the intervention without an additional delay. This modification did not result in a change to our Statement of Work.

We also added the Ann Arbor VA Health System as a recruitment site to this project in an effort to help ease staff burden and would be beneficial in reaching our recruitment goals. We do not think this will affect the budget, as the number of participants recruited between the Ann Arbor VA and the Detroit VA will now be split and no new staff will need to be hired as a result of this change (staff will split their time between the two sites). Both of these changes received approval from the

6. PRODUCTS

Nothing to Report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

• *What individuals have worked on the project?*

Name: Project Role: Researcher Identifier (e.g. ORCID ID): Nearest person month worked: Contribution to the project:	Mark A. Ilgen, PhD Principal Investigator 3 Dr. Ilgen has reviewed study materials, assisted in the refining and revision of the intervention manuals and measures, provided oversight in protocol and study procedures, and attended project meetings.
Name: Project Role: Researcher Identifier (e.g. ORCID ID): Nearest person month worked: Contribution to the project:	Jennifer Olson-Madden, PhD Site-PI (Denver & Colorado Springs) 4 Dr. Olson-Madden has facilitated the overall protocol and study coordination of the Denver sites, including in the review of study measures and materials, including the intervention manual, hiring of staff, overseeing any necessary study-related purchases, co-leading bi-weekly study organization phone meetings, and the preparation and review of regulatory documents.
Name: Project Role: Researcher Identifier (e.g. ORCID ID): Nearest person month worked: Contribution to the project:	Felicia Kleinberg, MSW IRB Coordinator (previous) 4 Ms. Kleinberg assisted in revising the protocol and creating study materials (e.g., consent forms, recruitment letters) for review by the USAMRMC RCS, has attended and participated in project meetings, and assisted with the initial write-up of local IRB paperwork. Please note, Ms. Kleinberg left the position in September 2014.

Name: Project Role: Researcher Identifier (e.g. ORCID ID): Nearest person month worked: Contribution to the project:	Amanda Price Project Manager 5 Mrs. Price assisted in revising the protocol and creating study materials for review by the USAMRMC RCS, has attended and participated in project meetings, and has assisted in modifying study materials including study measures, intervention manuals, and risk management protocols. Ms. Price also helped complete the IRB submissions for the University of Michigan, the Ann Arbor VA, and the Detroit VA.
Name: Project Role: Researcher Identifier (e.g. ORCID ID): Nearest person month worked: Contribution to the project:	Linda Mobley, MS IRB Coordinator (current) 2 Mrs. Mobley assisted in revising the protocols and study materials, attended project meetings, and has helped to complete the IRB submissions for the University of Michigan, the Ann Arbor VA, and the Detroit VA.
Name: Project Role: Researcher Identifier (e.g. ORCID ID): Nearest person month worked: Contribution to the project:	Ariel Friese, MS, LPC Project Coordinator (Denver & Colorado Springs) 5 Ms. Friese has worked on preparation, review and submission of regulatory documents, participation in bi-weekly study organization phone meetings, coordinated communication with project partners, recruitment of potential candidates for project positions, budget creation and management.
Name: Project Role: Researcher Identifier (e.g. ORCID ID): Nearest person month worked: Contribution to the project:	Emily Yeagley, MS, MPH Project staff 1 Ms. Yeagley assisted with the revision of the intervention manuals and attended project meetings.
Name: Project Role: Researcher Identifier (e.g. ORCID ID): Nearest person month worked: Contribution to the project:	Jing Wang, MS Data Manager 1 Ms. Wang reviewed study measures and continues to develop systems for project databases and electronic data and storage.

• Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

YES. Please see Other Support pages attached in the Appendices section.

- *What other organizations were involved as partners?*

Organization Name: Denver Research Institute

Location of Organization: Denver, CO

Partner's contribution to the project (identify one or more):

- Facilities (e.g., project staff use the partner's facilities for project activities);
- Collaboration (e.g., partner's staff work with project staff on the project);

8. SPECIAL REPORTING REQUIREMENTS

Please find an updated version of the QUAD CHART in the appendices.

9. APPENDICES

- a. Other Support**
- b. Quad Chart**

Changes in Other Support for Dr. Ilgen:

1. Effort ended on NIH/NIDA R01 DA026029 (PI – Blow).
2. Effort ended on NIH/NIAAA R01 AA018659 (PI – Blow).
3. Effort ended on Henry M. Jackson Foundation/DoD BAA-10-1 (PI – King).
4. Effort ended on VA HSR&D IAC 09-055-2 (PI – Ilgen and Timko).
5. Effort ended on VA HSR&D IIR 04-104-2 (PI – Valenstein).
6. Effort ended on VA HSR&D IAC 09-047 (PI – Ilgen).
7. Effort started on NIH/NIDA R01 DA033397 (PI – Ilgen).
8. Effort started on DoD W81XWH-14-1-0005 (PI – Ilgen).
9. Effort started on VA QUERI (PI – Ilgen).
10. Effort started on VA HSR&D CRE-010 (PI – Timko).

OTHER SUPPORT

ILGEN, MARK

University yearly evaluation of the effort distribution between the UM and the VA is represented by the calendar months reported on other support. MOU is on file.

ACTIVE

University Of Michigan Projects:

(Ilgen, M.)	04/01/11 – 03/31/16	2.3 calendar
NIH/NIDA R01 DA029587	\$324,428	
Psychosocial Pain Management during Addictions Treatment to Improve Outcomes		

This randomized control trial is designed to determine the efficacy of a group based cognitive-behavioral pain management intervention in comparison to a Supportive Psychoeducation Control (SPC) group in individuals with co-occurring pain and substance use disorders recruited at the start of residential treatment program.

(Ilgen, M.)	05/01/13 – 02/28/17	2.3 calendar
NIH/NIDA R01 DA033397	\$416,125	
Medical Marijuana: Longitudinal Trajectories in Use, Pain and Functioning		

With the ongoing policy debate and the growing popularity of medical marijuana programs in the United States, it is essential to understand the ramifications of medical marijuana use for individuals who seek access to it. The proposed study will identify a cohort of 800 individuals who are seeking to obtain medical marijuana and examine their substance use (marijuana and other drug use), pain (pain level and behavioral pain tolerance), HIV risk profile, functioning (mental, physical, employment, and legal functioning), and health service use over the course of two years. The resulting data will inform the debate surrounding medical marijuana use and could help shape strategies to identify and intervene with individuals at risk for problems related to substance use.

(Ilgen, M.)	12/30/13 – 12/29/18	3.4 calendar
DoD/USAMRMC – W81XWH-14-1-0005	\$1,250,319	(1.2 calendar
Intervening to Reduce Suicide Risk in Veterans with Substance Use Disorders		cost shared with the VA)

It is crucial to develop, refine, and evaluate empirically-based strategies for addressing suicide risk among

active duty and former members of the U.S. armed forces. Military and active duty soldiers with SUDs are at clear elevated risk for suicide but, currently, no clear interventions exist to decrease risk of suicide in these individuals. This study will provide a first-of-its-kind evaluation of the impact of a CBT intervention to reduce risk of suicidal thoughts and behaviors for Veterans with SUDs who are at elevated risk for suicide.

Veterans Health Administration Projects:

(Chermack, S.) VA Health Services Research and Development (HSR&D) Application IIR 09-333-2 Impact of Interventions to Reduce Violence and Substance Abuse among VA Patients	09/01/11 – 02/28/15 \$230,107	0.4 calendar
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The primary objectives of this study are to examine the impact on both substance use and violence outcomes of: a) an acute treatment phase integrated Motivational Interviewing-Cognitive Behavioral Treatment intervention (MI-CBT); and b) MI-CBT plus a violence and substance use prevention Continuing Care intervention (MI-CBT+CC) intervention. The results will enhance the development and implementation of effective violence prevention interventions to be incorporated into VA SUD treatment settings which will have a significant impact on the lives of Veterans and their families.

(Ilgen, M.) Veterans Health Administration-QUERI Opioid Prescribing in the VHA before and After the New Opioid Safety Initiative	09/01/14 – 08/31/15 \$99,929	1.8 calendar
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The purpose of the proposed project is to study changes in prescribing practices following the Opioid Safety Initiative for all patients and to determine the degree to which opioid prescribing practices change for patient with substance use disorders, who are at particularly high risk for opioid-related adverse outcomes.

(Timko, C.) VA Health Administration–HSR&D, CRE-010 TeleMonitoring to Improve Substance Use Disorder Treatment After Detoxification	07/01/14 – 06/01/15 \$330,682	0.6 calendar
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This is a randomized trial of a telephone intervention to designed help Veterans with Substance Use Disorders successfully transition from receiving a medical detox to specialty Substance Use Disorder treatment. Effects of the intervention will be examined on post-baseline treatment utilization, substance use and functioning.

OVERLAP

None

Changes in Other Support for Dr. Blow:

1. Effort ended on NIH/NIDA R01 DA026029 (PI – Blow).
2. Effort ended on NIH/NIDA R01 DA029587 (PI – Ilgen).
3. Effort ended on NIH/NIAAA R01 AA015154 (PI – Blow).
4. Effort ended on State of Michigan Grant #1 (PI – Blow).
5. Effort started on NIH/NIAAA R01 AA023122 (PI – Blow).
6. Effort started on DoD W81XWH-14-1-0005 (PI – Ilgen).
7. Effort started on Case Western Reserve University/DoD W81XWH-14-2-0007 (PI – Blow).

OTHER SUPPORT

BLOW, FREDERIC C

University yearly evaluation of the effort distribution between the UM and the VA is represented by the calendar months reported on other support. MOU is on file.

ACTIVE

University Of Michigan Projects:

(Blow, F.)	07/20/10 – 06/30/15	0.96 calendar
NIH/NIAAA R01 AA018659	\$414,966	
Optimizing Alcohol Brief Interventions in the ED: Computer vs. Clinician Delivery		

The proposed study will use computerized screening via touch-screen computer tablets with audio to recruit 750 inner-city ED patients screening positive for at-risk or problem alcohol use. The aims of the study are to develop and refine tailored motivational brief interventions that are parallel in structure but have varied delivery modalities (computer vs. therapist) for patients with at-risk or problematic alcohol use, and to conduct a randomized controlled trial comparing the efficacy of these BI approaches (C-BI, T-BI, control) on subsequent alcohol consumption and alcohol consequences, including alcohol-related injury, mental and physical-health functioning, and HIV risk behaviors at 3-, 6-, and 12-months post-ED visit.

(Blow, F.)	09/20/13 – 08/31/18	1.9 calendar
NIH / NIAAA / DoD R01 AA023122	\$432,165	(1.2 calendar
Preventing Alcohol/Prescribed Drug Misuse in the National Guard: Web and Peer BI		cost shared with the VA)

National Guard members, especially those who have been combat-deployed, are at high risk for developing alcohol- and prescription-related drug problems. The use of novel Web-based interventions combined with either Web-based boosters or Peer support sessions, can have a major public health impact for the National Guard, as well as the overall military, and can provide state-of-the-art techniques to prevent and intervene on these problems in the general population.

(Ilgen, M.)	12/30/13 – 12/29/18	0.84 calendar
DoD/USAMRMC – W81XWH-14-1-0005	\$1,250,319	
Intervening to Reduce Suicide Risk in Veterans with Substance Use Disorders		

It is crucial to develop, refine, and evaluate empirically-based strategies for addressing suicide risk among active duty and former members of the U.S. armed forces. Military and active duty soldiers with SUDs are at

clear elevated risk for suicide but, currently, no clear interventions exist to decrease risk of suicide in these individuals. This study will provide a first-of-its-kind evaluation of the impact of a CBT intervention to reduce risk of suicidal thoughts and behaviors for Veterans with SUDs who are at elevated risk for suicide.

(Blow, F.)	09/01/14 – 08/31/19	3.0 calendar
Case Western Reserve University / DoD/USAMRMC–	\$444,927	
W81XWH-14-2-0007		
Early Intervention to Reduce Alcohol Misuse and Abuse		
In the Ohio Army National Guard		

The proposed project is a fully-powered randomized controlled trial of a Web- and text-based alcohol brief intervention (WT-BI) versus and Enhanced Usual Care (EUC) condition for Ohio National Guard members who meet criteria for unhealthy drinking in the previous three months.

Veterans Health Administration Projects:

(Chermack, S.)	09/01/11 – 02/28/15	0.24 calendar
VA Health Services Research and Development	\$230,107	
(HSR&D) Application IIR 09-333-2		
Impact of Interventions to Reduce Violence and		
Substance Abuse among VA Patients		

The primary objectives of this study are to examine the impact on both substance use and violence outcomes of: a) an acute treatment phase integrated Motivational Interviewing-Cognitive Behavioral Treatment intervention (MI-CBT); and b) MI-CBT plus a violence and substance use prevention Continuing Care intervention (MI-CBT+CC) intervention. The results will enhance the development and implementation of effective violence prevention interventions to be incorporated into VA SUD treatment settings which will have a significant impact on the lives of Veterans and their families.

OVERLAP

None

Changes in Other Support for Dr. Bohnert:

1. Effort ended on UM Injury Research Center (PI – Bohnert).
2. Effort ended on NIH/NIDA R01 DA026029 (PI – Blow).
3. Effort started on NIH/NIDA R34 DA035331 (PI – Bohnert).
4. Effort started on NIH/NIAAA R01 AA018659 (PI – Blow).
5. Effort started on NIH/NIDA R01 DA029587 (PI – Ilgen).
6. Effort started on DoD W81XWH-14-1-0005 (PI – Ilgen).
7. Effort started on NIH/NIAAA R01 AA023122 (PI – Blow).
8. Effort started on CDC IPA 14IPA1405517 (PI – Bohnert).

OTHER SUPPORT

BOHNERT, AMY

University yearly evaluation of the effort distribution between the UM and the VA is represented by the calendar months reported on other support. MOU is on file.

ACTIVE

University of Michigan Projects:

(Bohnert, A.)	03/01/14 – 02/28/17	2.4 calendar
NIH/NIDA R34 DA035331	\$169,750	
Developing a prescription opioid overdose prevention intervention		

This behavioral intervention development project aims to expand and refine a three session intervention to prevention prescription opioid overdoses among individuals in residential addictions treatment and to conduct a pilot randomized controlled trial of the intervention compared to an equal attention control condition.

(Blow, F.)	07/20/10 – 06/30/15	0.6 calendar
NIH/NIAAA R01 AA018659	\$414,966	(concurrent
Optimizing Alcohol Brief Interventions in the ED:		With HSR&D
Computer vs. Clinician Delivery		CDA 09-204)

The proposed study will use computerized screening via touch-screen computer tablets with audio to recruit 750 inner-city ED patients screening positive for at-risk or problem alcohol use. The aims of the study are to develop and refine tailored motivational brief interventions that are parallel in structure but have varied delivery modalities (computer vs. therapist) for patients with at-risk or problematic alcohol use, and to conduct a randomized controlled trial comparing the efficacy of these BI approaches (C-BI, T-BI, control) on subsequent alcohol consumption and alcohol consequences, including alcohol-related injury, mental and physical-health functioning, and HIV risk behaviors at 3-, 6-, and 12-months post-ED visit.

(Ilgen, M.)	04/01/11 – 03/31/16	0.24 calendar
NIH/NIDA R01 DA029587	\$324,428	
Psychosocial Pain Management During Addictions Treatment to Improve Outcomes		

This randomized control trial is designed to determine the efficacy of a group based cognitive-behavioral pain management intervention in comparison to a Supportive Psychoeducation Control (SPC) group in individuals with co-occurring pain and substance use disorders recruited at the start of residential treatment program.

(Ilgen, M.)
DoD/USAMRMC – W81XWH-14-1-0005
Intervening to Reduce Suicide Risk in Veterans with
Substance Use Disorders

12/30/13 – 12/29/18
\$1,250,319

0.48 calendar

It is crucial to develop, refine, and evaluate empirically-based strategies for addressing suicide risk among active duty and former members of the U.S. armed forces. Military and active duty soldiers with SUDs are at clear elevated risk for suicide but, currently, no clear interventions exist to decrease risk of suicide in these individuals. This study will provide a first-of-its-kind evaluation of the impact of a CBT intervention to reduce risk of suicidal thoughts and behaviors for Veterans with SUDs who are at elevated risk for suicide.

(Blow, F.)
NIH / NIAAA / DoD R01 AA023122
Preventing Alcohol/Prescribed Drug Misuse in the
National Guard: Web and Peer BI

09/20/13 – 08/31/18
\$432,165

0.48 calendar

National Guard members, especially those who have been combat-deployed, are at high risk for developing alcohol- and prescription-related drug problems. The use of novel Web-based interventions combined with either Web-based boosters or Peer support sessions, can have a major public health impact for the National Guard, as well as the overall military, and can provide state-of-the-art techniques to prevent and intervene on these problems in the general population.

(Bohnert, A.)
Center for Disease Control and Prevention - IPA
14IPA1405517

09/01/14 – 08/31/15
\$14,498

1.2 calendar

The assignment will allow CDC to gather crucial information to address the following key areas of the Prescription Drug Overdose team's strategic direction: 1) Effective monitoring and surveillance of opioid prescribing and associated health outcomes. 2) Analyses to determine key drivers of opioid pain reliever overdose and effective strategies to prevent opioid pain reliever overdose. In addition, the assignment will allow CDC and University of Michigan researchers to examine the relationship between opioid prescriptions and clinical outcomes in order to inform opioid prescribing guidelines as well as recommendations for coordinated care for patients with pain.

Veterans Health Administration Projects:

(Bohnert, A.)
Veterans Health Administration, HSR&D CDA 09-204
Prescription Opiates in Overdoses among VHA
Patients

04/01/10 – 03/31/15
\$99,250

6.6 calendar

The aims of this project are: 1) to analyze pharmacy data to document and examine patterns in VHA prescribing of opiate analgesics; 2) to analyze clinical and mortality data to assess trends in opiate analgesic overdoses; and 3) to apply epidemiologic research methods to understand risk factors for opiate analgesic overdose in the VHA.

OVERLAP

None

Changes in Other Support for Dr. Chermack:

1. Effort ended on NIH/NIAAA R01 AA018122 (PI – Walton).
2. Effort ended on NIH/NIDA R01 DA026029 (PI – Blow).
3. Effort ended on VA HSR&D IAC 09-047 (PI – Ilgen).
4. Effort started on DoD W81XWH-14-1-0005 (PI – Ilgen).
5. Effort started on NIH/NIMH R01 MH103244 (PI – King).

OTHER SUPPORT**CHERMACK, STEPHEN**

University yearly evaluation of the effort distribution between the UM and the VA is represented by the calendar months reported on other support. MOU is on file.

ACTIVE**University of Michigan Projects:**

(Blow, F.)	07/20/10 – 06/30/15	0.22 calendar
NIH/NIAAA R01 AA018659	\$414,966	
Optimizing Alcohol Brief Interventions in the ED: Computer vs. Clinician Delivery		

The proposed study will use computerized screening via touch-screen computer tablets with audio to recruit 750 inner-city ED patients screening positive for at-risk or problem alcohol use. The aims of the study are to develop and refine tailored motivational brief interventions that are parallel in structure but have varied delivery modalities (computer vs. therapist) for patients with at-risk or problematic alcohol use, and to conduct a randomized controlled trial comparing the efficacy of these BI approaches (C-BI, T-BI, control) on subsequent alcohol consumption and alcohol consequences, including alcohol-related injury, mental and physical-health functioning, and HIV risk behaviors at 3-, 6-, and 12-months post-ED visit.

(Ilgen, M.)	04/01/11 – 03/31/16	0.18 calendar
NIH/NIDA R01 DA029587	\$324,428	
Psychosocial pain management during addictions treatment to improve outcomes		

The proposed project will determine the efficacy of a cognitive-behavioral pain management intervention targeting individuals with co-occurring pain and substance use disorders who will be recruited at the start of a residential treatment episode. This proposed efficacy study will provide crucial data on a brief, innovative method designed to improve outcomes in the large numbers of individuals with both substance use disorders and chronic pain.

(King, C.)	02/01/11 – 01/31/16	0.88 calendar
Henry M. Jackson Foundation / Department of Defense BAA-10-1	\$68,455	
Post Admission Cognitive Therapy (PACT) for the Inpatient Treatment of Military Personnel with Suicidal Behaviors: A Multi-Site Randomized Controlled Trial		

This study is a randomized controlled trial comparing the impact of cognitive behavioral therapy versus treatment as usual in reducing suicidal behaviors in military personnel following an inpatient psychiatric stay.

(Ilgen, M.)
DoD/USAMRMC W81XWH-14-1-0005
Intervening to Reduce Suicide Risk in Veterans with
Substance Use Disorders

12/30/13 – 12/29/18
\$1,250,319

0.18 calendar

It is crucial to develop, refine, and evaluate empirically-based strategies for addressing suicide risk among active duty and former members of the U.S. armed forces. Military and active duty soldiers with SUDs are at clear elevated risk for suicide but, currently, no clear interventions exist to decrease risk of suicide in these individuals. This study will provide a first-of-its-kind evaluation of the impact of a CBT intervention to reduce risk of suicidal thoughts and behaviors for Veterans with SUDs who are at elevated risk for suicide.

(King, C.)
NIH/NIMH R01 MH103244
Electronic Bridge to Mental Health (eBridge) for College
Students

08/11/14 – 07/31/19
\$497,783

0.96 calendar

We propose to conduct a large-scale randomized controlled intervention trial across multiple universities to determine the impact of eBridge on college students' readiness to seek mental health treatment, linkage to mental health treatment, and mental health outcomes. We will also determine the extent to which the online counseling mediates intervention effectiveness.

Veterans Health Administration Projects:

(Chermack, S.)
VA Health Services Research and Development
(HSR&D) Application IIR 09-333-2
Impact of Interventions to Reduce Violence and
Substance Abuse among VA Patients

04/01/11 – 03/31/15
\$230,107

1.8 calendar

The primary objectives of this study are to examine the impact on both substance use and violence outcomes of: a) an acute treatment phase integrated Motivational Interviewing-Cognitive Behavioral Treatment intervention (MI-CBT); and b) MI-CBT plus a violence and substance use prevention Continuing Care intervention (MI-CBT+CC) intervention. The results will enhance the development and implementation of effective violence prevention interventions to be incorporated into VA SUD treatment settings which will have a significant impact on the lives of Veterans and their families.

OVERLAP

None

Changes in Other Support for Dr. Valenstein:

1. Effort ended on NIH/NIA P01 AG031098 (PI – Cutler).
2. Effort ended on DoD W81XWH-11-2-0059 (PI – Hunt).
3. Effort ended on McCormick Foundation
4. Effort ended on State of Michigan Project #3 (PI – Neal)
5. Effort ended on VA HSR&D IIR 08-325 (PI – Valenstein).
6. Effort ended on VA HSR&D IIR 08-116 (PI – Kilbourne).
7. Effort ended on VA HSR&D SDP 10-047 (PI – Valenstein).
8. Effort started on NIH/NIAAA R01 AA023122 (PI – Blow).
9. Effort started on BCBSM Foundation (PI – Valenstein).
10. Effort started on DoD W81XWH-14-1-0005 (PI – Ilgen).
11. Effort started on NIH/NIMH R34 MH103447 (PI – Pfeiffer).
12. Effort started on State of Michigan Project #9 (PI – Dalack).
13. Effort started on NIH/NIMH R01 MH09669 (PI – Aikens/Piette).
14. Effort started on DoD/MSU W81XWH-11-PHTBI-BAPHA (PI – Kees).
15. Effort started on Bristol-Myer Squibb Foundation (PI – Kees).
16. Effort started on VA HSR&D IIR 12-109 (PI – Valenstein).
17. Effort started on VA HSR&D IIR13-310 (PI – Valenstein).
18. Effort started on VA QUERI RRP 12-511 (PI – Zivin).
19. Effort started on VA QUERI RRP 12-505 (PI – Pfeiffer).

OTHER SUPPORT**VALENSTEIN, MARCIA**

University yearly evaluation of the effort distribution between the UM and the VA is represented by the calendar months reported on other support. MOU is on file.

ACTIVE**UNIVERSITY OF MICHIGAN**

(Blow, F.)	09/20/13 – 08/31/18	1.8 calendar
NIH / NIAAA / DoD R01 AA023122	\$432,165	
Preventing Alcohol/Prescribed Drug Misuse in the National Guard: Web and Peer BI		

National Guard members, especially those who have been combat-deployed, are at high risk for developing alcohol- and prescription-related drug problems. The use of novel Web-based interventions combined with either Web-based boosters or Peer support sessions, can have a major public health impact for the National Guard, as well as the overall military, and can provide state-of-the-art techniques to prevent and intervene on these problems in the general population.

(Valenstein, M.)	10/15/13 – 06/15/15	0.6 calendar
BCBSM Foundation	\$94,814	
Assessing Tailored Mental Health Management Support for Primary Care		

The goal of this project is assess the feasibility and effectiveness of a tailored mental health care management (TaMMs) intervention for patients in safety-net primary care clinics. This intervention is designed to support the

care of large numbers of patients, increasing or decreasing the intensity of support services, to deliver "just enough" and "just in time" support of their mental health treatment.

(Ilgen, M.)	12/30/13 – 12/29/18	0.6 calendar
DoD/USAMRMC – W81XWH-14-1-0005	\$1,250,319	
Intervening to Reduce Suicide Risk in Veterans with Substance Use Disorders		

It is crucial to develop, refine, and evaluate empirically-based strategies for addressing suicide risk among active duty and former members of the U.S. armed forces. Military and active duty soldiers with SUDs are at clear elevated risk for suicide but, currently, no clear interventions exist to decrease risk of suicide in these individuals. This study will provide a first-of-its-kind evaluation of the impact of a CBT intervention to reduce risk of suicidal thoughts and behaviors for Veterans with SUDs who are at elevated risk for suicide.

(Pfeiffer, P.)	07/15/14 – 05/31/17	0.6 calendar
NIH / NIMH R34 MH103447	\$125,000	
Peer mentorship to reduce suicide risk following psychiatric hospitalization		

Risk of suicide is significantly elevated during the period of time immediately following inpatient psychiatric treatment. This study will develop and pilot test a peer mentorship intervention to reduce the risk of suicide among patients psychiatrically hospitalized at the University of Michigan.

(Dalack, G.)	10/01/14 – 09/30/15	0.36 calendar
State of Michigan Community Health HHS Project #9	\$84,913	
Tailored Mental Health Management Support for Primary Care		

This project provides a continuum of monitoring and intervention services, tailored to the needs of patients with depression and anxiety, with the most intensive services being targeted to the highest-risk patients.

(Aikens/Piette)	09/18/12 – 06/30/17	1.2 calendar
NIH / NIMH R01 MH096699	\$382,442	
Telemonitoring Enhanced Support for Depression Self-Management		

This is an RCT to compare the effectiveness of telemonitoring support with care partners to usual care on depression severity outcomes among low-income primary care patients.

(Kees, M.)	09/30/12 – 09/29/15	0.11 calendar
DoD/MSU – W81XWH-11-PHTBI-BAPHA	\$27,862	
Risk, Resiliency, and Coping in National Guard Families		

Examine risk and resilience in National Guard military families across the longitudinal course of a deployment cycle, with up to three years follow-up.

(Kees, M.)	11/01/12 – 11/30/15	0.24 calendar
Bristol-Myer Squibb Foundation	\$201,757	
Implementing Peer Advisors for Veteran Education (PAVE)		

This grant will support the implementation and evaluation of the Peer Advisors for Veteran Education (PAVE), a peer-to-peer program that connects student Veterans on participating campuses with upper class student Veterans (Peer Advisors) who can help identify emerging mental health issues and assist Veteran students in navigating college life and accessing appropriate mental health services and other supportive resources.

DEPARTMENT OF VETERANS AFFAIRS

(Valenstein, M.)	01/01/13 – 12/30/16	1.09 calendar
VA Health Services Research and Development	\$361,559	
(HSR&D) IIR 12-109		
Veteran College Students Mental Health and Academic Achievement		

This project aims will be to 1) Assess cross-sectional and longitudinal prevalence of mental health symptoms, hazardous alcohol use, and levels of wellbeing among a *representative* sample of Veteran and comparison students. 2) Assess Veteran students' use of VA and non-VA mental health services (including college mental health services), treatment preferences, and perceived treatment barriers, and 3) Assess cross-sectional and longitudinal *associations* between Veteran students' mental health symptoms, treatment, and academic performance.

(Valenstein, M.)	10/01/14 – 03/31/18	0.6 calendar
VA Health Services Research and Development	\$347,455	
(HSR&D) IIR 13-310		
Veteran Peer-Assisted Computerized Cognitive Behavioral Therapy for Depression		

The purpose of this study is to conduct a Hybrid Type I RCT of Peer-Supported cCBT (PS-cCBT) versus enhanced usual care (EUC) for 330 patients with new episodes of depression diagnosed in primary care at three VA sites and their CBOCs. Our Primary Specific Aims are to 1) compare PS-cCBT versus EUC on symptomatic, functional and recovery-oriented outcomes, and 2) compare PS-cCBT versus EUC on acquisition of depression coping skills, initiation and continuation of antidepressant medication, and initiation and completion of more intensive traditional psychotherapy (contingent on symptom level).

(Zivin, K.)	09/01/11 – 02/28/15	0.33 calendar
VA Health Services Research and Development	\$430,000	
(HSR&D) IIR 10-176-3		
Risk of Depression Among Veterans with Depression		

The study aims are to 1) To examine the risks and causes of mortality among VA patients with and without depression; 2) To characterize the impact of modifiable health behaviors (smoking, drinking, and obesity) on the relationships between depression and all-cause mortality, mortality from cardiovascular disease, and mortality from cancer; 3) Examine associations between receipt of depression treatment and mortality.

(Kilbourne, A.)	03/01/12 – 05/31/15	0.27 calendar
VA Health Services Research and Development	\$324,986	
(HSR&D) IIR 10-340-3		
Life Goals Collaborative Care to Improve Health Outcomes in Mental Disorders		

The primary goal of this study is to determine whether VA patients with SMI receiving Life Goals Collaborative Care (LGCC), a program that combines customized behavioral change strategies with chronic care

management for SMI will experience improved medical outcomes, mental health outcomes, or improved health behaviors.

(Zivin, K.)	11/01/13 – 02/28/15	0.6 calendar
VA MH-QUERI RRP 12-511	\$99,302	
Employment support needs of VA primary care patients with depression and anxiety		

The purpose of this project is to assess VA primary care (PC) patient employment characteristics among those with depression and anxiety by examining differences in 1) employment status 2) perceived barriers to and facilitators of employment, and 3) use of and preferences for employment services.

(Pfeiffer, P.)	11/01/13 – 02/28/15	1.2 calendar
VA MH-QUERI RRP 12-505	\$90,942	
Technology-assisted peer support for recently hospitalized depressed Veterans		

The purpose of this project is to 1) assess the feasibility and acceptability of a peer specialist and technology-assisted care management program for patients following hospitalization for depression, 2) examine the program's impact on the quality of patient care and outcomes, and 3) assess barriers and facilitators to adoption, implementation, and maintenance of the program.

OVERLAP

None

Changes in Other Support for Dr. Olson-Madden:

1. Effort ended on HRSA/CO/UCB 101HATBIP (PI – Banich).
2. Effort ended on VA Office of Rural Health (PI – Wahlberg).
3. Effort ended on DHHS/HRSA/CO 1HATBIP1125855 (PI – Brenner).
4. Effort ended on DHHS/HRSA 1HATBIP0900557 (PI – Brenner).
5. Effort started on DoD/University of Michigan W81XWH-14-1-0005 (PI – Olson-Madden)

OTHER SUPPORT**OLSON-MADDEN, JENNIFER****ACTIVE**

(Olson-Madden, J.)	12/30/13 – 12/29/18	6 calendar
DoD/USAMRMC/University of Michigan	\$484,376	
W81XWH-14-1-0005		
Intervening to Reduce Suicide Risk in Veterans with Substance Use Disorders		

It is crucial to develop, refine, and evaluate empirically-based strategies for addressing suicide risk among active duty and former members of the U.S. armed forces. Military and active duty soldiers with SUDs are at clear elevated risk for suicide but, currently, no clear interventions exist to decrease risk of suicide in these individuals. This study will provide a first-of-its-kind evaluation of the impact of a CBT intervention to reduce risk of suicidal thoughts and behaviors for Veterans with SUDs who are at elevated risk for suicide.

OVERLAP

None