CAREER PLAN

A. Research Background

My primary career goal is to develop as an independent health services researcher with expertise in the implementation of evidence-based mental health practices (EBPs) for treating various psychiatric and substance use disorders in primary care medicine. My research training in clinical psychology at the University of Nevada, Reno focused mainly on understanding pathways to medical utilization (O'Donohue & Cucciare 2005b), how psychological factors impact medical care utilization (O'Donohue & Cucciare, 2005c); and understanding models for integrating EBPs into medical settings (O'Donohue, Cummings, Cucciare, Cummings, & Runyan, 2006).

I am currently completing the second year of my postdoctoral research fellowship at the HSR&D Center for Health Care Evaluation at the VA HSR&D Center of Excellence. While a fellow, I have added to my prior research experience by learning ways in which to use computer-based technology to enhance the dissemination and implementation of EBPs (Cucciare, Weingardt, Villafranca, in press; Cucciare & Weingardt, 2007).

B. Research Interests

My research interests center on the dissemination and implementation of EBPs in primary care medicine. While a doctoral student in clinical psychology at the University of Nevada, Reno, I developed an interest in exploring the roles of psychological factors in patient presentations. As a health services research fellow at CHCE, I have had the fortunate opportunity to work with Dr. Kenneth Weingardt in the promising application of computer technology to promote the sustained adoption of EBPs within VA primary care settings. As a result, my interest in implementation has increasingly focused on utilizing novel, effective, and highly transportable computer-based strategies to implement EBPs in primary care medical settings. The training and research plan outlined in this application for a CDA - 2 are expressly and purposively designed to build upon as well as extend my previous research efforts and growing interest in this domain of health services research. I hope to have the opportunity to pursue the activities outlined in the proposed CDA-2, as my mentors and I feel they will provide me with the training necessary to develop an independently funded health services research career within the VA health care system.

C. VA Service and Other Involvement

I have been with the VA Health Care System since September of 2005 when I began my predoctoral internship in clinical psychology at the VA Palo Alto Health Care System (VAPAHCS) (APA-accredited). Following the successful completion of my internship, I transitioned into a postdoctoral research fellowship in health services research at the HSR&D Center for Health Care Evaluation (CHCE) at VAPAHCS. While a fellow, I have served (and continue to do so) on the VA Mental Health Executive Committee and VA My Recovery Plan Workgroup. In these roles, I have worked with Dr. Weingardt on the development of the mental health content of MyHealtheVet and MyRecoveryPlan which will be distributed nationally. As a collaborator on these projects, I continue to play a substantial role in overseeing the implementation of informational/educational materials and screening tools for common mental health problems presented by veterans (e.g., SUDs, PTSD, depression, and polysubstance use) on MyHealtheVet. One of the main goals of the VA My Health<u>e</u>Vet Mental Health Executive Committee, of which I am a member, is to develop the content of My Recovery Plan which will be an interactive set of web-based tools that will allow veterans who have behavioral or mental health concerns to track important aspects of their self-care and professional care.

I also served as member of the organizational committee for a recent VA conference entitled, "Meeting the Mental Health Needs of OIF/OEF Returnees." This conference was held on June 20, 2007 at the VA Palo Alto. The purpose of the conference was to provide an overview of the mental health needs of OIF/OEF returnees and provide information on how best to modify current treatment approaches to meet the needs of this population of veterans. A

central issue that emerged from this conference was the importance of providing veterans with access to brief mental health care in VA primary care medicine.

D. Relationship of Research Interests of Applicant and Mentors

My primary research interest is focused on the dissemination and implementation of EBPs in medical settings, particularly primary care medicine. An important factor motivating this CDA-2 application is my desire to receive expert mentorship and consultation in a number of substantive areas of health services research that will enable me to pursue this program of research over the course of my career as a VA health services researcher (see section H). The mentors and consultants listed below were selected based on the relevance of their expertise to my training and research goals outlined in this application for a CDA-2. I am fortunate to have exceptional and ideally-matched mentors at the VA Palo Alto's Center for Health Care Evaluation and VA Puget Sound CESATE, including Drs. Kenneth R. Weingardt, Susan Frayne, and Daniel Kivlahan. These three scholars and I share common interests in (a) the implementation of EBPs into medical settings, (b) treating veterans presenting with alcohol misuse and SUDs, and (c) examining the cost-effectiveness of various methods of treatment implementation. Given the interdisciplinary nature of the research activities proposed in this CDA, it is important that I have mentors and consultants with various disciplinary backgrounds.

(Primary Mentor) Kenneth R. Weingardt, Ph.D., is Associate Director of the Program Evaluation and Resource Center at the VAPAHCS and Consulting Assistant Professor at Stanford University School of Medicine. He is also a core investigator at the CHCE. Dr. Weingardt is an expert in the use of web-based technology to facilitate the implementation of evidence-based practices in psychiatric and substance abuse treatment (Cucciare, Weingardt, & Villafranca, in press; Cucciare & Weingardt, 2007; Weingardt, 2004; Weingardt, Villafranca, & Levin, 2006). He has several research projects currently funded by the National Institute on Drug Abuse (NIDA) and VA HSR&D. His most recent grant funded project VA SDP is a clinical trial focused on using a web-based training protocol for teaching SUD counselors cognitive behavioral therapy for depression. Dr. Weingardt's expertise in using web-based technology to implement and disseminate EBPs is crucial to my development as a VA health services with expertise in implementation science. Furthermore, his expertise in the use of computer-based strategies to deliver mental health interventions will be invaluable over the course of this proposed application for a CDA. Thus, he has agreed to serve as my primary mentor and will provide ongoing consultation, mentorship and supervision at every stage of his CDA project. This will include guidance on issues of research design and methodology, instrument selection, participant recruitment, data collection, and the design and implementation of the technology-based behavioral health intervention itself. He will also provide ongoing supervision regarding the complex interpersonal and organizational issues that are critical for the success of implementation research.

(Co-Mentor) Susan Frayne, M.D., M.P.H. is the Associate Director of the Women's Health Center at the VA Palo Alto and an Associate Professor in the Division of General Internal Medicine at Stanford University School of Medicine. She is also core faculty at the CHCE. She is a nationally recognized expert in the treatment of mental health problems in primary care medicine (Frayne, Freund, Skinner, Ash, & Moskowitz, 2004; Frayne, Skinner, Lin, & Ash, 2004) and the interplay between mental and physical health problems (Frayne et al., 2004; Hankins et al., 1999). She has completed an HSR&D CDA and Advanced CDA, and has extensive experience training and mentoring VA health services researchers. Dr. Frayne's expertise in treating mental health problems in primary care will be invaluable to the development of the studies proposed in this CDA, and will play an important role in ensuring that the implementation of our interventions will be feasible in primary care settings.

(Co-Mentor) Daniel Kivlahan, Ph.D. is director of the Center of Excellence in Substance Abuse Treatment and Education at VA Puget Sound Health Care Center and Co-Clinical Coordinator of the SUD-QUERI. He is also an Associate Professor at the University of

Washington's Department of Psychiatry and Behavioral Sciences. Dr. Kivlahan's vast scholarship has focused on screening, assessing, and implementing evidence-based practice guidelines for the treatment of SUDs in VA primary care (Bradley et al., 2007; Bradley et al., 2006; Bray et al., 2007). He will provide mentorship in several areas pertinent to the proposed research including guiding the methodological and conceptual development of the treatment approaches to fit maximally with the dissemination objectives of the SUD-QUERI, helping with the development of my grant conceptualizations and writing skills, and advising and guiding the measurement of alcohol misuse in VA primary care. He will also review and provide feedback on all manuscripts prior to submission for publication.

Consultants. **Rudolph Moos, Ph.D.** is a VA HSR&D Career Scientist, inaugural (1999) recipient of the Undersecretary's Award for Outstanding Achievement in Health Services Research, and Professor of Psychiatry and Behavioral Sciences at Stanford University School of Medicine. I plan to meet with Drs. Moos every two weeks during the initial planning phase of the study to discuss general methodological issues involved in conducting treatment outcomes studies. *He will also provide concentrated consultation during the planning phase of the primary research activities and toward the end of the proposed clinical trial, particularly on the issue of patient follow-up (conducting phone interviews) and intrepreting health care utilization patterns.* Dr. Moos has a longstanding history of succesfully tracking and following-up with substance using patients (Finney, Hahn, & Moos, 1996; Moos, King, & Patterson, 1996; Ouimette, Finney, & Moos, 1997) and examining their health care utilization patterns (Moos, Finney, Ouimette, & Suchinsky, 1999; Moos & Moos, 2005a; Moos & Moos, 2005b; Moos & Moos, 2007) which is invaluable to the proposed health services training and research in this CDA-2 application.

Mark W. Smith, Ph.D. is a Health Economist and Co-Principal Investigator in the Health Economics Resource Center (HERC). He is an expert in cost-effectiveness analysis, and estimating and identifying the cost of delivering and using mental health services. He currently provides weekly consultation to the PI on these issues and this will continue through the proposed CDA. **Alex Sox Harris, Ph.D.** of the Center for Health Care Evaluation, VAPAHCS and Stanford University School of Medicine is an expert statistician who has agreed to provide statistical consultation for this CDA. He will provide consultation regarding advanced data analytic approaches to examine the proposed research findings. Dr. Harris currently meets with me once a week regarding statistical approaches relevant to clinical trial data (e.g., multiple regression techniques, mixed effects regression models, ANCOVA) and this will continue over the course of the proposed CDA. **David Renfro, R.N., M.S.** is the clinical coordinator and Nurse Leader in Ambulatory Care at the VA Palo Alto. He will provide invaluable consultation on the training of nurses in the VA Palo Alto's primary care clinic (also known as the General Medicine Clinic or GMC). He will help with recruitment, scheduling of training sessions, and will organize overall nurse involvement in the proposed CDA-2 research. **Lars Osterberg, M.D.** is Chief of General Internal Medicine at the VA Palo Alto Health Care System and a Clinical Assistant Professor of Medicine at the Stanford University School of Medicine. His research focuses on vulnerable populations and patient access to care; innovations in practices of medical care; and patient adherence to medications. He will provide expert guidance in the implementation of our intervention into VA primary care; and logistic, administrative, and managerial support for the successful completion of the proposed research.

E. Potential Impact of Proposed CDA on the Improvement and Evaluation of Veteran Health Care and Health Policy.

The integration of evidence-based mental health practices into primary care is a top National VA Priority (OPCS, 2007). Implementation of brief alcohol counseling into VA primary care is now a National VA Performance measure (OPCS, 2007). This priority reflects the large percentage of veterans presenting with alcohol misuse in VA primary care settings (Bradley, et al., in press). The findings from this proposed research program will help us better determine the relative effectiveness of two methods for delivering a brief, motivation-based intervention for

treating alcohol misuse in VA primary care. Furthermore, the findings of the proposed CDA may have large scale implications for how to design and implement brief, evidence-based mental health treatments for a wide variety of psychological problems common to VA primary care (e.g., anxiety disorders). These findings may also help inform the types of methods of treatment delivery that can be used effectively to treat these problems in VA primary care. For example, if the proposed studies show that a nurse-administered procedure is more cost-effective than a self-administered intervention (i.e., computer), the VA may wish to consider using this methodology to train nurses in brief, evidence-based mental health practices for treating other common mental health problems seen in primary care.

F. Expected Benefits of Proposed Research for both VA and Applicant's Research Program

The research proposed in this CDA application may have many important benefits to the VA. First, the primary proposed studies may allow us to determine whether face-to-face delivery of a motivation-based intervention significantly improves patient outcomes relative to the less resource intensive computer-based intervention. This may have important implications for selecting treatments to be implemented into VA primary care for alcohol misuse. The proposed studies may also provide data that help VA health managers to select treatment and methods of intervention delivery that can serve in addition to or as the performance measure for brief alcohol counseling, thereby improving the treatment of alcohol misuse in primary care. Second, although this study is concerned specifically with treating alcohol misuse, the findings from this study may have large scale health policy implications for implementing brief, EBPs for the treatment of other common mental health problems in VA medical settings. For example, the proposed studies will demonstrate the feasibility of (a) a web-based training for teaching nurses a brief, motivational intervention for treating alcohol misuse, and (b) the cost-effectiveness of nurse- and computer-administered interventions for treating alcohol misuse in VA primary care. Should our study demonstrate these to be useful methods for training and delivering an intervention, their effectiveness could be evaluated for addressing other common mental health problems such as depression, post traumatic stress disorder, and polysubstance use in VA medical settings. Furthermore, the results of this study may add to existing findings (e.g., TIDES projects; Rubenstein et al., 2006) showing the feasibility of nurse administered interventions for treating common mental health problems (e.g., depression).

This CDA will allow me to develop a research program using technology to facilitate the implementation of EBPs into VA medical settings. My long-term goal is to develop a program of research that identifies effective methods of implementing EBPs in VA medical settings for treating high prevalence mental health problems. Second, my long-term career goal is to develop the skills to conduct high quality research and to secure ongoing funding as an independent VA health services researcher. The proposed research and career plan will provide me with expert mentorship and experience in substantive areas of health services research necessary to achieve this career goal.

G. Commitment and Goals for Professional Advancement within the VA.

I am committed to developing a VA health services research career with expertise in clinical trials and implementation science. The VA is recognized as a premier health care provider and is a model for integrating mental and physical health care. Aspects of VA health care such as being integrated and having electronic patients records (CPRS), along with easy access to the web make it an ideal place for me to develop a research career in integrated care. Furthermore, a top health care priority for VA is to continue to improve mental health care in primary care settings. My current and long-term research goals are consistent with this priority and I intend to continue to use my research skills to improve the mental health care of veterans presenting to VA medical settings. I also intend to continue participating in the development and implementation of National VA mental health care initiatives such as MyHealtheVet and My Recovery Plan. I hope to develop expertise in and to use web-based technology to implement

EBPs in VA primary care medicine and to thereby translate my research findings into advanced practice and veteran well-being.

H. Specific Formal and Informal Training Activities and Objectives, and Specific New Skills to be obtained. (see Table 1 for a Timeline Summary of Training Activities by year of CDA Award).

Through in depth discussion with my mentors, I have identified six training goals that will be the focus of my CDA - 2. The areas of training that will be emphasized over the course the proposed CDA-2 include: (1) training in research design, methodology, and statistical analysis for conducting treatment outcome studies; (2) training in health services research methodology, health care economics, and interpretation of health care utilization patterns; (3) obtaining advanced training in motivational interviewing for the treatment of substance use disorders; (4) developing expertise in the dissemination and implementation of mental health interventions in VA primary care; (5) developing expertise in scientific and grant writing; and (6) further development of my professional identity and expertise in research ethics.

Training Goal #1: Obtain Advanced Training in Research Design, Methodology, and Statistical Analysis Pertaining to Conducting Treatment Outcome Studies.

I will purse formal and informal training activities to achieve this training goal. Formal coursework will occur at Stanford University School of Medicine, Department of Health Research, and Policy. Each class occurs quarterly and includes 1 to 4 units. I plan to audit these courses when the option is available. These courses will include: **HRP 251 (3 units)- Design and Conduct of Clinical Trials**: this is an advanced course for researchers that covers issues related to clinical trials including the scientific rationale, recruitment of subjects, techniques for randomization, data collection techniques, interim monitoring, and reporting of results. The emphasis in this course is on the theoretical underpinnings of clinical research and the practical aspects of conducting clinical trials. **HRP 252 (3 units) - Outcomes Analysis:** this graduate course teaches methods for conducting empirical studies that use large existing medical, survey, and other databases to ask both clinical and policy-related questions. This class will be particularly useful in helping me navigate, organize, and develop databases consisting of VA data.

I will also seek out a number of informal training opportunities including informal workshops in biostatistics held at Stanford University. These workshops cover methods for analyzing longitudinal data, including Kaplan-Meier methods, Cox regression, hazard ratios, time-dependent variables, longitudinal data structures, profile plots, missing data, modeling change, MANOVA, repeated-measures ANOVA, GEE, and mixed models. *I also plan to meet with Drs. Moos every two weeks during the initial planning phase of the study to discuss general methodological issues involved in conducting treatment outcomes studies. Dr. Moos will also provide focused mentoring for improving follow-up rates and conducting phone interviews toward follow-up. I also currently meet weekly with Dr. Sox-Harris to consult on methodological and advanced statistical strategies relevant to treatment outcome studies and plan to continue to do so over the course of my CDA.*

Training Goal #2: Training in Health Services Research Methodology, Health Care Economics, and Interpretation of Health Care Utilization Patterns.

I plan to obtain training on the core health services research methodologies that are relevant to my proposed studies. I will focus on developing expertise in evaluating the impact of mental health interventions on VA health care utilization, cost-effectiveness research methodologies, and strategies for identifying and interpreting VA health care utilization patterns. To achieve this training goal, I will complete formal coursework at Stanford University School of Medicine, Department of Health Research, and Policy including: **HRP 392 (4 units): Analysis of Cost, Risks, and Benefits of Health Care** - this course is for advanced graduate students and focuses on teaching the principal evaluative techniques for health care, including utility assessment, cost-effectiveness analysis, cost-benefit analysis, and decision analysis. Emphasis

is on the practical application of these techniques. **ECON 226 (1 unit): Economics of Health and Medical Care** - this course is an introduction to the field of health economics. This class covers some of the key concepts that health economists use to analyze health care markets.

I will also attend VA Cyber Seminars and Courses held regularly by HERC. HERC offers various cyber courses in health economics including methods of economic evaluation of health care with special reference to VA datasets. These topics include cost measurement, VA and non-VA cost and utilization data sources, methods of economic evaluation, and measurement and modeling of health care outcomes. I will also consult with Dr. Smith weekly (and as needed) to discuss methods for identifying the impact of brief mental health interventions on (a) VA healthcare utilization, and (b) research methodologies and statistical approaches for examining the cost-effectiveness of brief mental health interventions targeting alcohol misuse.

Training Goal #3: Obtain Advanced Training in Motivational Interviewing and Substance Use Disorders. *I will seek advanced training in motivational interviewing (MI) from Paula Wilbourne, Ph.D. (who trained with one of the originators of MI, Dr. William Miller) who is the director of Addiction Treatment Services at the VAPAHCS. She regularly conducts workshops on MI for staff and researchers. These courses will provide the PI with much needed expertise in MI (e.g., how to effectively administer, provide training in, and implement MI in various medical settings). Dr. Wilbourne is has agreed to hold in-person and phone meetings with me when necessary. I will also provide her with manuscripts and other study materials for review.*

I will also seek additional training in MI from the Motivational Interviewing Network of Trainers. Drs. William Miller and Stephen Rollnick provide year round training opportunities in MI. I plan to attend at least two workshops on Advanced Motivational Interviewing held in December and June of the first year of CDA funding.

I will attend weekly forums held by the Center for Health Care Evaluation at the VAPHCS to develop expertise in substance use disorders among veterans. Forum topics commonly revolve around such issues as (a) epidemiology (e.g., incidence, prevalence) of substance use among veterans; (b) methods for conducting program evaluation of existing systems of care for treating substance use in the VA system; and (c) important issues relevant to persons with SUDs such as common psychiatric and physical co- morbidities. In addition, I plan on attending the Research Society on Alcoholism (RSA) and the VA HSR&D's annual conferences to develop expertise in SUDs, particularly alcohol use disorders.

Training Goal #4: Develop Expertise in Dissemination and Implementation of Mental Health Interventions in VA Primary Care. *I have developed research collaborations with several VA primary care providers with expertise in various aspects of disseminating and implementing mental health interventions into primary care medicine. Specifically, I will meet with my co-mentor, Dr. Susan Frayne, twice a month (and as needed) to discuss the unique challenges of disseminating mental health intervention in primary care medicine (see section D). I also plan on meeting with David Renfro, R.N., M.S. to discuss issues relevant to logistics of integrating mental health interventions into primary care medicine. I will meet with Drs. Kenneth Weingardt weekly and Daniel Kivlahan monthly (via phone with Dr. Kivlahan) to discuss issues related to screening and implementing interventions for alcohol misusing veterans in VA primary care. Dr. Weingardt will provide additional expertise in strategies for enhancing the sustained adoption of mental health interventions among primary care staff.*

I plan to regularly attend the Society for General Internal Medicine's (SGIM) annual conference. Their mission is to improve patient care, education, and research in primary care and general internal medicine. Their annual conference includes presentations from interdisciplinary researchers and providers on methods for improving mental health treatment in primary care. I also plan to regularly attend the Quality Enhancement Research Initiative (QUERI) meetings based at the Center for Health Care Evaluation. From these meetings and collaborations, I will learn the QUERI process for implementing research findings and evidence-based clinical practices.

Training Goal #5: Develop Expertise in Scientific and Grant Writing. *I plan to develop my scientific and grant writing skills over the course of my CDA. This aim will be achieved largely through working closely with my mentors and core consultants to draft and review manuscripts and grant applications. In addition, I plan to attend workshops and classes in scientific and grant writing offered at the annual RSA meeting, and to attend one formal course through the Stanford University School of Medicine including:*

HRP 214 (1 unit): Scientific Writing: This is an advanced course that provides opportunities for intensive feedback on professional writing skills with an emphasis on manuscript development.

I will attend workshops offered through Stanford and NIH, which are offered continuously throughout the academic year, which focus on various aspects of grant writing. They cover the fundamental principles of successful grant writing, including factors that increase the likelihood of success, the most common reasons that grant applications fail, how to make an application "reviewer friendly", and how to meet the needs of the reviewers and the funding agency.

Training Goal #6: Further Development of my Professional Identity and Expertise in Research Ethics. *I will work closely with my mentors and core consultants to formulate a program of research that is well-informed and centered on improving mental health care for veterans presenting to primary care with high prevalence mental health problems (e.g., alcohol misuse). All three of my mentors have exemplary programs of research and have demonstrated a high level of productivity and quality, scientific flexibility, and mentorship ability that will most certainly help me achieve this professional goal.*

A second important aspect of my professional development will be to obtain further training in research ethics. Weekly and monthly research meetings with mentors and core consultants will provide a rich opportunity for me to discuss and obtain new knowledge on conducting responsible and ethical research. I will also take a course in ***Medical Ethics (Med 225; 1 unit)*** *offered through Stanford University's School of Medicine which provides a forum for scientists to familiarize themselves with institutional policies/practices and professional standards that define scientific integrity.*

Linkage between Proposed Training and Research Activities. *The training activities proposed in this application for a CDA - 2 (see Table 1) were expressly designed to support the proposed research activities listed in Table 2. For example, Year 1 formal and informal training activities will focus on clinical trials methodology, training in MI, as well as initial training in health economics issues. These training activities will provide direct support for conducting study 1 (phase one) in Years 1 and 2, as well as conducting study 1 (phase two) in Years 2 and 3. Year 2 will include more focused training on health services and health economics issues pertinent to completing the second objective (impact on health care utilization) of study 1 (phase one) and completing study 1 (phase two). Training activities in Years 3 and 4 will focus on outcomes analysis, grantsmanship, and preparing manuscripts for peer review. These training activities will support statistical analyses to be conducted on study 1 (phase one and two) outcome data, as well as secondary studies 3 and 4; grant writing in Year 3 (and possible resubmissions in Year 4); and manuscript submissions planned for Years 3 and 4.*

Table 1: Proposed Training Activities by CDA Year

Training, Research, and Grant Activities	***Year 1***	***Year 2***	***Year 3***	***Year 4***
Formal Training	*- Stanford University School of Medicine -HRP 251: Clinical Trials - Motivational Interviewing (MI) Network – Workshop Training in MI – University of New Mexico -HRP 214: Scientific Writing -HERC Cyber Seminars and Courses*	*- Stanford University School of Medicine courses - NIH and Stanford grant writing workshops (Held in DC and on Web). -HRP 392: Analysis of Costs, Risks, Benefits of Health Care -Econ 226: Economics of Health & Medical Care -HERC Cyber Seminars and Courses*	*- HERC Cyber Seminars and Courses - MED 225: Medical ethics -Stanford workshop in Biostatistics -HRP 252: Outcomes Analysis*	*As needed (see Table 2)*
Informal Training	*-Weekly VA Palo Alto HSR&D Forums on SUDs -QUERI VA Palo Alto Meetings -SUD-QUERI Workgroup Meetings -Workshops in advanced Motivational Interviewing (MI)*			
Collaborations	*-Collaborate with CHCE mentors and investigators on ongoing treatment outcome projects (participate on data analysis and authoring manuscripts) -Collaborate with colleagues and mentors at Stanford University School of Medicine, University of Nevada, Reno, and CHCE on intra – and extramural grant development. -Collaborate with VA Primary Care Staff on manuscript preparation/ data collection/ and grant development*			
Annual Conference Meetings	*-Research Society on Alcoholism (RSA) -Society for General Internal Medicine (SGIM) -VA HSR&D Annual Meetings*			
Mentorship	*-Meetings with Drs. Weingardt & Frayne on Implementation Science and Primary Care Integration. -Meetings with Dr. Kivlahan on Brief Screening and Interventions for Alcohol Misuse in Primary Care -Consultation with Dr. Moos on Treatment Outcome Methodology -Consultation with Dr. Sox - Harris on Advanced Statistical Strategies -Consultation with Dr. Smith on Issues related to Health Economics -Consultation with Mr. Renfro, MS, RN on Nurse Training in VA Primary Care*			

I. Future Research Plans and Ambitions

My primary career goals are to become a leader in the area of implementing EBPs for treating psychiatric and SUD disorders in VA primary care. I would like to continue to conduct health services research to support the VA as it moves forward with its National priority to implement EBPs into various medical settings, especially primary care settings. Upon receipt of the proposed CDA, I would focus on pursuing health services training and on conducting research that may have implications for VA national health care practices and policies. Furthermore, upon the granting of the proposed CDA, I would immediately begin seeking VA grant funding to continue my research program. I plan further to develop research collaborations throughout the VA with researchers in nursing, general internal medicine, emergency medicine, and health economics, and to participate on VA national committees focused on screening,

assessing, and treating veterans with SUDs and other psychiatric disorders in medical settings. I hope to have the opportunity to incorporate the findings of the studies proposed in this CDA to help shape health care policies within the VA health care system, with the ultimate goal of improving health care for veterans presenting to medical settings with SUDs and other psychiatric disorders.

J. Percent of Time to be Devoted to Research and other Concurrent Commitments to the Local VA Medical Center.

Under the sponsorship of my post doctoral research fellowship in health services research, I currently devote 100% of my time to research. As a recipient of a CDA, I would continue to dedicate 100% of my time to research.

RESEARCH PLAN

Rationale for Proposed Research Plan:

The research activities proposed in the following section(s) are aimed at developing a program of research focused on developing expertise in conducting clinical trials and the implementation of EBPs in primary care medicine. EBPs have been defined by the American Psychological Association as mental health practices that integrate the best available empirical and clinical expertise (APA Presidential Task Force, 2006; pp. 273). Common examples of EBPs include Motivational Interviewing for substance use disorders (Miller & Rollnick, 2002) and Cognitive Behavioral Therapy for depression (Beck, Rush, Shaw, & Emery, 1987).

The proposed research program is closely aligned with recent VA initiatives to integrate the delivery of EBPs into primary care medicine (VA Office of Patient Care Services OPCS, 2007). The most recent manifestation of this effort is an emphasis on improving the treatment of alcohol misuse in VA primary care. Therefore, I have proposed a series of primary and secondary research studies focused on both (a) supporting VA's initiative to identify and implement "best practices" for treating alcohol misuse in VA primary care, and (b) to support my development as a health services researcher with expertise in implementation science.

A. Overview of Primary Research Objectives (secondary study objectives are described in the Research Plan):

Study 1 (phase one): *In the first proposed study, we plan to conduct a randomized clinical trial to compare the relative effectiveness of three treatment conditions - brief motivational intervention administered via nurse, via computer, and treatment-as-usual (TAU). This study will have two aims: (1) train and supervise nurses in a brief, motivational intervention for treating alcohol misuse in VA primary care and (2) to examine whether nurse- and/or computer-administered motivational interventions are more effective than TAU for treating alcohol misuse in primary care.*

Hypothesis 1: Veteran participants in both experimental conditions will show more improvements in primary (i.e., alcohol quantity and frequency) and secondary outcomes (i.e., identifying relapse cues, consequences of alcohol misuse, psychological distress, health status/quality of life, health care utilization) from baseline to 6-months post-treatment when compared to TAU.

Hypothesis 2: Veteran participants in the nurse-administered condition will demonstrate greater improvements in primary and secondary outcomes from baseline to 6-months post-treatment when compared to the computer-administered and TAU conditions.

Study 1 (phase two): *In a second study, we propose examining the relative cost-effectiveness of these three interventions for treating alcohol misuse in a VA primary care clinic. We have two hypotheses for this study:*

Hypothesis 1: Both experimental treatment conditions will prove to be more cost-effective than TAU.

Hypothesis 2: The nurse-administered feedback condition will prove to be more cost-effective than the computer-administered and TAU condition.

Study 2 or Alternate Study 2: *Should we find support for the hypotheses in study 1 (phase one and two), we propose conducting a third primary study to extend these findings by conducting a multi-site RCT to examine the relative (cost) effectiveness of both experimental conditions and a TAU control group. Should the hypotheses of study 1 (phase one and two) not be (or partially) supported by the results, we would propose an alternate study 2, which would be to develop and pilot test additions to the proposed interventions such as "booster" in-person or telephone sessions.*

B. Background:

Most problem drinkers do not present to specialty SUD treatment, but do access medical care through primary care providers (Cunningham & Blomqvist, 2006). Thus, primary care providers (PCPs) can play a key role in identifying and treating problem drinking. PCPs role in identifying and treating problem drinking is a particularly important issue in the VA Health Care System as recent research shows significant increases in alcohol misuse in active duty military personnel, and specifically OIF/OEF returnees (Seal et al., 2007).

Research demonstrates that primary care physicians can effectively deliver brief, evidence-based practices for treating a wide variety of psychological problems in medical settings such as alcohol misuse (Schermer et al., 2006). However, time constraints do not often allow busy physicians to spend the required amount of time with patients who screen positive for alcohol misuse or other psychiatric conditions in order to effectively deliver brief interventions. This finding has led to a search for alternatives to using physicians to administer screens and interventions for the reduction of alcohol use. Several studies support the use of nurses as providers who can effectively administer brief, evidence-based interventions to patients screening positive for alcohol misuse (Babor, Higgins-Biddle, Dauser, Higgins, & Burleson, 2005).

There is also similar empirical support for the use of computer-based brief motivational interventions for treating alcohol misuse (Copeland & Martin, 2004; Marks, Cavanagh, & Gega, 2007). Cunningham, Humphreys, and Koski-James (2000) studied the effectiveness of a brief, computer administered assessment and personalized feedback program for reducing alcohol misuse. Users accessed the program through the internet from their personal computer. Results showed a significant drop in self-reported use of alcohol at 3-months follow-up when compared to a no treatment control group. Based on these results, we hypothesize that both nurse- and computer-administered motivation-based assessment and feedback will significantly reduce alcohol misuse among veterans screening positive on the AUDIT-C. We predict that veterans participating in the nurse-administered condition will demonstrate greater reduction in alcohol use and improvements in other important health outcomes when compared to veterans participating in the computer-based condition and receiving treatment-as-usual. On the other hand, computer-based interventions should be less expensive, so the relative cost-effectiveness of these two delivery formats remains to be determined.

There are no studies directly comparing the relative effectiveness of these two types of interventions. Considering the significant resources required for nurse-administered alcohol misuse interventions in a busy VA primary care clinic, it is critical to establish whether such interventions significantly improve outcomes over those administered entirely via computer technology or current treatment-as-usual.

The Relationship between Alcohol Misuse, Health Outcomes, and Health care Utilization. Alcohol misuse has a negative effect on a person's physical and psychological health. Patients who misuse alcohol have higher rates of liver disorders (i.e., alcohol hepatitis), cardiovascular problems, bone loss, and certain types of cancers (i.e., esophagus, liver, and colon) (Fleming, et al., 1997). Patients who misuse alcohol also have higher rates of psychological distress (Compton et al., 2007). Compton and colleagues interviewed over 43,000 US adults and found that patients who met criteria for alcohol dependence had significantly higher rates of symptoms associated with common psychological problems such as depression

and anxiety than those who did meet this diagnostic criterion. It has been hypothesized that alcohol misuse increases negative affect, impairs problem solving skills, and aggravates impulsive personality traits, possibly through effects on serotonergic transmission (Brady, 2006).

The negative health effects of alcohol misuse are associated with increased use of health care resources. Larson et al. (2006) found that alcohol misuse is strongly associated with increased use of both outpatient and inpatient (emergency room and overnight hospital visits) health care. Research shows that alcohol-misusing patients who receive treatment demonstrate significant reductions in health care utilization post treatment, thus treatment of alcohol misuse can, in some cases, reduce health care utilization and costs (Fleming et al., 2002; Kane, Wall, Potthoff, & McAlpine, 2004). However, studies have found that reductions in utilization post treatment are gradual and may take several months to years to observe (Kane et al., 2004; Senft et al., 1997).

Brief, Motivation-based Interventions for Treating Alcohol Misuse. The phrase "brief psychotherapy intervention" generally refers to short protocols consisting of between 1 and 4, 10-to-50 minute sessions (Dunn, 2003). Many studies support the use of brief interventions for helping alcohol misusing patient reduce their alcohol use (Fleming et al., 1997; Senft et al., 1997). Of the brief psychotherapies, Motivational Interviewing (MI) is perhaps the most widely studied and effective (Miller, Wilbourne, & Hetema, 2003). Its main objective is to help patients resolve the ambivalence that is often associated with making many important lifestyle changes such as reducing alcohol use (See Hettema, Steele, & Miller, 2005 for a review; Miller & Rollnick, 2002).

Studies also show MI (and motivational interventions in general) to be an effective, brief intervention for reducing alcohol quantity and frequency in patients presenting to primary care (Dunn, Deroo, & Rivara, 2003; Miller et al., 2006; Senft et al., 1997, Vasilaki, Hosier, & Cox, 2006 for reviews). Senft et al. (1997) conducted a randomly controlled trial to study the effectiveness of a brief motivational session for alcohol misusing patients. The interventions consisted of a brief screen (i.e., AUDIT) followed by a 15-minute motivational feedback session provided by a health counselor. Patients in the treatment condition reported a greater reduction in alcohol quantity and use at 6-months follow up than controls (Kaner et al., 2007).

Primary care is a fast-paced patient care setting, leaving relatively little time for providers to spend treating psychiatric disorders. Thus, one-session versions of MI have been developed and evaluated for helping patients reduce their alcohol use (Aharonovich et al., 2006; Rollnick, Heather, & Bell, 1992; Senft et al., 1997). Abridged versions of MI-based interventions use the principles of MI to deliver short (e.g., 15-30 minutes) sessions, most often incorporating an assessment and feedback component (AF). Assessment consists of: obtaining information on the quantity and frequency of alcohol use; and providing the patient with normative comparisons of their alcohol use. Feedback typically consists of providing normative comparisons of the patient's drinking behavior, descriptions of the consequences of alcohol misuse (e.g., acute and chronic effects of alcohol use on physical and psychological well-being), and individualized alcohol use recommendations. MI interventions typically also offer options for reducing alcohol use and use strategies for building patients' confidence that they can succeed in reducing their alcohol use (see Senft et al., 1997; Weingardt & Wilbourne, 2007).

Significance: In 2006, the National Commission for Prevention Priorities sponsored by the Centers for Disease Control and the Agency for Healthcare Research and Quality identified brief alcohol counseling as one of the top ten national prevention priorities based on clinically preventable burden of diseases and the cost-effectiveness of interventions. However, previous efforts to implement brief alcohol counseling in primary care medicine largely have been unsuccessful mainly due to the (a) complexities of assessment and treatment procedures employed (Aalto et al., 2003; Gomel et al., 1998), such as requiring staff to remember complex algorithms for scoring screening tools, (b) employing nontraditional primary care staff to conduct counseling (e.g., health counselors), and (c) utilizing procedures that significantly interrupt the

work flow of the primary care clinic (e.g., scheduling extra patient visits to conduct brief alcohol counseling v. conducting the counseling during regularly scheduled visits) (see Bradley et al., 2006). The studies proposed in this CDA application will address these important barriers to implementation. For example, we plan to utilize a relatively simple (three questions scored by a computer) alcohol screening procedure (AUDIT-C) that is currently employed in VA primary care; nurse providers already working in VA primary care; and research procedures that minimally impact on primary care work flow (e.g., providing treatment to patients attending regularly scheduled primary care visits). The ultimate goal of the proposed research plan is to identify the most cost-effective method for delivering a brief, evidence-based intervention for treating veterans presenting to VA primary care with alcohol misuse, and purse research efforts toward their implementation within VA primary care.

Relevance to Veterans Health: Recognizing both the prevalence and numerous physical and negative health outcomes associated with alcohol misuse, the VA Office of Quality and Performance and VA/HSR&D Substance Use Disorders Quality Enhancement Research Initiative (SUD-QUERI, 2006) implemented the first step in promoting a standardized approach for addressing this health problem, i.e., a Nationwide Alcohol Misuse Screening Performance Measure (i.e., AUDIT-C) (Bradley et al., 2006). The AUDIT-C consists of the first three items of the 10-item AUDIT (Babor & Grant, 1989). HSR&D investigators studied the impact of alcohol screening in 21 VA networks and found that 93% of VA outpatients were screened for alcohol misuse. While as many as 20-30% screened positive, only 42% reported follow-up that included brief alcohol counseling (Bradley et al., 2006). As a result, the VA has recently implemented a National performance measure for brief alcohol counseling following a positive screen for alcohol misuse (Bradley et al., 2006). The Office of Patient Care Services (OPCS, 2007) recommends that all veterans screening positive on the AUDIT-C receive brief alcohol counseling the same calendar day as the positive screen as of FY08.

C. Work Accomplished:

Pilot 1. In a first pilot study, we identified a group of 7 VA primary care providers (2 physicians and 5 nurses) to participate in a focus group to determine interest in learning brief, motivational interventions for alcohol misuse. Providers participated in a structured presentation on the prevalence of alcohol misuse among veterans in VA primary care, an estimate of the increase in prevalence with the arrival of OIF/OEF returnees, and the effectiveness of brief, MI-based interventions for treating alcohol misuse in primary care. **Results.** All 7 providers endorsed the need for implementing interventions for alcohol misuse in primary care. Providers further stressed the importance of (a) adequate nurse training in the intervention and on-going supervision, (b) flexibility of training methods in motivational interventions (e.g., use of CD-ROM that could be taken home), and (c) developing a treatment and research procedure that has minimal impact on existing primary care work flow.

Pilot 2. Next, we conducted a pilot study to determine the feasibility of training 3 VA primary care nurses using our online training program. We developed an online training course (www.bmiforsuv.org) and distributed copies of the course on CD-ROM. The course includes a pre/ post knowledge test, the training content, and instructions for obtaining 3 CME credits (received upon completion). Nurses were provided both the intranet link to the course and a training CD-ROM, and instructed to complete the course within two weeks. **Results.** Results showed that nurses were able to complete the course within the allotted time and passed the knowledge test with (at least 80% correct).

Pilot 3. We obtained IRB approval from Stanford University Human Subjects protection, VA Palo Alto's Research Administration, the VA Palo Alto's Research Administration Nursing Subcommittee to conduct a small scale pilot study to examine the feasibility of implementing both the nurse- and computer-administered intervention in one VA primary care clinic (located at VA Palo Alto). Nurses from pilot 2 were included in this study. All nurse participants completed the online training within a week and successfully passed the knowledge test (a score of 80% or

better*). **Results.** At the present time, we have installed computer equipment (with the help of IRMS) in the Patient Resource Center located on the second floor of the GMC clinic. We have randomly assigned a small sample of veterans to the two intervention conditions. Patients were asked to complete a four question demographic worksheet, a measure of self-efficacy about changing their alcohol use, and a satisfaction questionnaire after receiving feedback. Preliminary findings show that our sample (n = 6) is primarily Caucasian (84%) and reports earning over $50,000 per year (67%) in annual income. All participants reported not currently being in treatment for a substance use disorder. In addition, our preliminary findings suggest that veterans' are equally satisfied with both methods of intervention and equally willing to change drinking behavior upon receiving either method of treatment. However, pilot participants receiving the computer-administered intervention report greater intention to attend an initial appointment with a substance abuse counselor. Note. Getting this pilot study "up and running" took longer than anticipated due to significant delays with IRMS implementing computer equipment in VA primary care and obtaining required permission to conduct the study. These issues have since been resolved.*

D. Work Proposed:

***Timetable of Proposed Activities:** In the following sections, I propose a series of primary and secondary research activities to be completed over the course of the CDA award (see pages 50 to 60 for a full description of these activities). These research activities are focused both on improving mental health treatment for alcohol misusing veterans in VA primary care, and providing me with the necessary research training and skills to develop into a health services researcher with expertise in conducting clinical trials and implementation science (also see Table 2 for a timetable of research activities). Each of the studies mentioned in this section is discussed in detail in the Research Plan.*

Year 1

***Primary Research Activities:** I plan to complete Pilot project 3 prior to the beginning of the CDA. Since the initial submission of this CDA application, we have focused on activities preparatory to research. We are currently recruiting patients and plan to have this project completed by the start of Year 1, in which case we will begin manuscript preparation. We will then focus on analyzing the data, and preparing a manuscript for internal CHCE review. We will begin setting up the infrastructure to support study 1 (phase one) which includes completing nurse recruitment and training in motivational interventions; and hiring and training a research assistant to conduct assessments, and manage the project patient flow. We will begin recruitment for study 1 (phase one) in this year (see page 50 for a full description of study 1).*

Year 2

***Primary Research Activities:** We will begin the 6-month follow-up process. Recruitment will be staggered such that follow-up can begin while conducting baseline assessments on new participants. We will complete database development for organizing baseline and 6-month data and preparing begin cleaning baseline data. I project that by the middle of Year 2, we will have completed recruitment and follow-up for study 1 (phase one). I will also begin obtaining necessary permissions to obtain data from VA National databases which are required for study 1 (phase two). I will engage in concentrated consultation with Dr. Smith to finalize the identification of cost variables required to conduct the cost-effectiveness analysis (i.e., study 1 (phase two)), and to begin database creation for this study. I will also begin conceptualizing NIH RO1 and VA IIR grant applications to seek funding for study 2, should the hypotheses of study 1 (phase one and two) be supported. Otherwise, we will begin preparations for conducting an alternative study 2 (see page 59 for a full description of study 2) investigating the effect of adding additional treatment components to the proposed intervention(s).*

***Secondary Research Activities:** I will begin reviewing several literatures to be included in study 3 (see page 60). I will provide each of my mentors and Dr. Moos an outline to obtain*

feedback on the conceptual layout of the manuscript. My intention is to begin writing an initial draft of this manuscript to be included in Year 3 grant submissions.

Year 3

Primary Research Activities: *I anticipate completing data collection for study 1 (phase one and two) by Year 3. This includes abstracting all necessary administrative data for study 1 (phase two). I will focus on preparing follow-up data from study 1 (phase one) and cost-effectiveness data from study 1 (phase two) for analyses. This will include data cleaning and addressing any missing data issues. By mid Year 3, I plan to have begun the data analyses process to begin examining the results of both studies. Initial examinations of outcome and cost data will be included in both Year 3 grant proposals designed to seek funding for study 2. Should the hypotheses of study 1 (both phases) be supported, I will begin developing collaborations at three VISN 21 primary care clinics (sites to be determined) in preparation for conducting a multi-site trial. Manuscripts describing the main outcomes of study 1 (phase one and two) will also be prepared and submitted for internal CHCE/HERC review. Once any revisions are addressed, I plan to submit these manuscripts for publications. I will also spend several months of Year 3 preparing RO1 and IIR grant applications to be submitted by June of Year 3. This will involve concentrated mentorship and consultation from my mentors and Dr. Moos on grant writing, and submitting these grant applications for internal CHCE review. Similarly, once revisions to both grant applications are made, I will submit them to the VA and NIH for funding consideration.*

Secondary Research Activities: *I plan to complete secondary study 3 and submit this manuscript for publication. I will begin collaborating with Drs. Weingardt and Trafton on secondary studies 4 and 5 (see page 60), respectively. Regarding secondary study 4, I will develop a data analysis plan with consultation from Drs. Sox-Harris and Weingardt, and begin conducting analysis. I will work with Dr. Weingardt to develop an outline of the manuscript and begin conducting a literature review for this empirical paper. This same process will be repeated with Dr. Trafton for beginning secondary study 5.*

Year 4

Primary Research Activities: Year 4 of my CDA award will focus on actively pursuing funding for study 2 or beginning a pilot study to examine modifications made in alternate study 2 (see pages 59,60 for a full description of alternate study 2). I will also focus on revising study 1 (phase one and two) manuscripts with the goal of submitting these empirical papers for peer-review. **Secondary Research Activities:** In collaboration with Drs. Weingardt and Trafton, I will complete manuscripts for secondary studies 4 and 5. I will submit these for internal CHCE review and make necessary revisions. I plan to complete final drafts of these papers and submit them for publication during this year of the CDA award.

Table 2: Proposed Research Activities by CDA Year.

Research Activities	Year 1	Year 2	Year 3	Year 4
Primary Study 1 (phase one)	*- begin training RAs/nurses/ Install second patient kiosk/ begin patient recruitment/ complete database development*	*-train RAs to conduct telephone 6-month follow-up assessments/ begin and complete follow-ups/ begin data entry for follow-up data/*	*-complete data entry/ Prepare database for analysis/ begin stats. analysis outcomes/complete first draft of manuscript/ submit for internal review*	*-submit manuscript for publication*
(phase two)		*-begin focused consultation with Dr.*	*-complete data collection/ prepare data*	*-submit manuscript for*

		Smith (HERC)/finalize data to be included in analysis/VHA National Databases permissions/ database creation/begin importing cost variables	*for analysis/ analysis/ complete first draft of manuscript/submit for internal CHCE/HERC review*	*publication*
Study 2 (or alternate study 2)		*-begin outlining IIR/RO1 grant submissions/*	*-integrate draft of secondary study 1 (lit review) with treatment outcome data from study 1 (phase one) in grant submissions or begin pilot phase of alternate study 2*	*-continue to purse funding for study 2 or complete pilot and/or begin trial for alternate study 2*
Secondary		*begin lit review for study 3; submit outline for internal review*	*complete study 3*	*complete studies 4 and 5*
Grant Proposals	*Study 1 (both phases) is being supported by CHCE*	*Study 1 (both phases) is being supported by CHCE*	*-submit IIR and RO1 to fund study 2 (submit June of year 3)*	*-grant resubmissions*

Primary Research Activities
Study 1 (phase one)

Objective 1:

Compare the relative effectiveness of a brief motivational intervention administered by trained nursing staff and a self-administered alcohol assessment and feedback tool accessed via computer to a treatment-as-usual (TAU) control condition. *The next step in my proposed research training is to evaluate the relative effectiveness of both methods of treatment delivery to a treatment-as-usual control condition in a randomized trial. We are currently completing a pilot study investigating the feasibility of implementing these two methods in primary care at VA Palo Alto (preliminary data are presented in section C). Our preliminary data suggest that both methods of intervention are feasible. In addition, we have taken some initial steps to begin preparation for conducting the clinical trial (e.g., we recently hired a research assistant, located office space in primary care).*

Aim 1. The first aim of study 1 (phase one) is to train and supervise nurses in a brief, motivational intervention for treating alcohol misuse in VA primary care.

Design and Methods Overview. We will identify 3-5 additional nurses working in the GMC at VA Palo Alto interested in participating in the web-based training (also available on CD-ROM) in brief, motivational interventions. We have already trained and recruited 3 nurses to participate in this study. We estimate that we will require a total of 6-8 nurses to complete the proposed clinical trial. Our pilot research shows that practicing nurses are willing and able to complete the online course. As in the case of our pilot study, nurse recruitment will be coordinated through clinical coordinator for the GMC clinic (David Renfro, MS, BS). Interested nursing staff will be asked to attend a brief initial meeting with the PI where they will receive a training CD-ROM and instructions for obtaining 3 CME credits. Nurses will be asked to complete an initial pretest on brief, motivation based techniques prior to beginning the course. This test (and course) was developed by Dr. Weingardt and his research team to assess initial knowledge in motivational interventions for treating substance use. Once the pretest is complete, nurses will be asked to complete the training within two weeks and provide the PI with evidence of successful completion of course (i.e., their CME certificate which is provided after successful passing the

post test knowledge exam). Participating nurses are required to score 80% or above to qualify for CME credits. The pre/post knowledge test are accessed and scored by the VA's Employee Education System (EES) – Online Learning Website (http://vaww.ees.aac.va.gov). It is important to note that nurses will be provided both the intranet web address and a CD-ROM so that they may chose to take the course during their tour of duty and/or at home. To prevent "drift" in the provision of the brief intervention, nurses will be required to attend a weekly, phone supervision meeting (moderated by the PI) after completion of the initial training to provide an opportunity for them to discuss and review MI-based techniques and concepts, ask questions, and report patient issues relevant to treatment.

Training Course. Our web-based program provides training in how to conduct brief, motivational interventions for substance abusing veterans*. The course was funded and developed by the VA in collaboration with the Program Evaluation Resource Center (PERC), Readjustment Counseling Services (RCS), and the Employee Education System (EES). Content development was validated by Drs. Wilbourne and Baer both experts in MI. The committee met regularly to validate content prior to the development of course modules.* The course was designed to train counselors how to use a web-based assessment tool to generate personalized feedback regarding an individual veteran's current level of substance use, and how to discuss this personalized feedback with the veteran in a way that will maximize the likelihood that he or she will decide to take positive steps towards change. The course has been approved by the VA Employee Education System (EES) for 3 hours of continuing education credit for nurses, psychologists, and social workers. Previews of the course are available on the VA Intranet at the project website www.bmiforsuv.org, and in Appendix A of this application.

The content of the course is arranged in four sequential modules: (1) Background on Substance Use Disorders, (2) Assessment, (3) Feedback, and (4) MI Basics. The Background on SUD module is designed to provide trainees with basic working knowledge about addictive disorders. It covers such topics as how to distinguish between abuse and dependence, how to identify substance-related problems, the relationship between SUDs and PTSD among combat veterans, and the various pathways to recovery that are available to clients who express interest in changing their patterns of substance use behavior.

The Assessment module provides training in how to use of the Assessment and Feedback Tool (or AFT) to generate personalized feedback. The content and structure of this module closely follows that of the AFT assessment itself, and includes information about what each set of items measures, where the item came from, and what function the assessment item serves in the feedback process. Similarly, the content and structure of the Feedback module follows that of the Personalized Feedback Report (PFR), and provides step-by-step guidelines about how best to engage patients in a productive discussion regarding the information contained in their personalized report. In addition to providing nurses with a basic understanding of the information contained in the PFR, the Feedback module is designed to train nurses how to deliver this feedback in a way that is consistent with the MI approach. In this respect, the feedback module adopts a situated learning approach in which nurses are taught the relevant clinical skills as they are applied by expert therapists in the context of realistic clinical case presentations. The final MI Basics module delivers didactic training regarding some of the fundamental concepts in MI, and makes extensive use of brief video role plays to demonstrate various MI micro skills (e.g., providing normative feedback, rolling with resistance). Again, detailed information regarding both the AFT (see Appendix B) and the online course can be found in the Appendices and on the project website www.bmiforsuv.org.

Knowledge Test. This is a straightforward test of knowledge that counselors obtain from completing the course. After completing the course, nurses should be able to: (a) distinguish between substance abuse and substance dependence, (b) explain the basic principles of Motivational Interviewing, (c) use a web-based tool to conduct brief, objective assessment of a

veterans substance use, and (d) deliver feedback about substance use in way that will maximize the likelihood that a veteran will take positive steps towards change.

Treatment Fidelity Check. *All nurses will be asked to submit 7 audiotapes sessions over the course of recruitment so that treatment fidelity may be examined. Seven sessions (using 8 intervention nurses) represents approximately 25% of the total sessions conducted by each nurse. This number was chose because it will allow us to examine treatment fidelity while minimizing coding workload. Audiotapes will be coded using the Motivational Interviewing Treatment Integrity (MITI) scale to assess treatment fidelity (MITI; Moyers, Martin, Manuel & Miller, 2002). The MITI is an empirically derived scale that measures therapist adherence to the principles and skills of MI. Using the coding manual developed by Moyers et al., trained research assistants will be asked to code the tapes once they have been submitted.*

Required Weekly Supervision. *Nurses who agree to participate in the study will be required to receive on going, weekly supervision in motivational interventions delivered via telephone.* Supervision will provide nurses with the opportunity to present and discuss specific patient cases, and conceptual and therapeutic issues related to using motivational-based interventions for alcohol-misusing veterans. Research shows that continued supervision is necessary in addition to initial training in motivational interventions to promote high-fidelity, long-term use of these treatment strategies (Miller et al., 2004). Our pilot research has found that nurses prefer phone meetings (rather than in-person meetings) because of the flexibility they allow. Prior to beginning supervision, I will hold an initial meeting with participating nurses to determine a time each week that nurses agree to meet for supervision and to discuss the purpose(s) of the regular supervision meetings. Supervision sessions will be held twice a week to prevent clinic "back up".

Aim 2: ***The second aim of study 1 (phase one) is to conduct a clinical trial comparing the relative effectiveness of a brief, motivational intervention administered by trained nursing staff and a self-administered AFT tool compared to a treatment-as-usual (TAU) control condition.***

Study Hypotheses. *We have two main hypotheses for objective 1.*

Hypothesis 1: Veteran participants in both experimental conditions will demonstrate significantly greater reductions in alcohol quantity and frequency, consequences of alcohol use, and psychological distress, along with increases in confidence in identifying relapse cues and health-related quality of life from baseline to 6-months post-treatment when compared to TAU. *Based on the findings of prior research (Neighbors, Larimer, & Lewis, 2004; Senft et al.,1997), we expect significant reductions in alcohol quantity and frequency reported by participants from baseline to post-treatment in the experimental conditions. In addition, we expect factors associated with reductions in alcohol quantity and frequency (confidence in identifying relapse cues, consequences of alcohol use, and symptoms of psychological distress) to improve significantly in both experimental groups from baseline to post-treatment.*

Hypothesis 2: Veteran participants in the nurse-administered condition will demonstrate significantly greater reductions in alcohol quantity and frequency, consequences of alcohol use, and psychological distress, along with increases in confidence in identifying relapse cues and health-related quality of life from baseline to 6-months post-treatment when compared to veterans in the computer-administered treatment and TAU conditions. *Veterans in the nurse-administered condition will receive both the printed feedback and have that feedback reviewed with them by a trained nurse. We expect the added component of nurse feedback will result in veterans demonstrating greater improvements in the above outcomes when compared to veterans in the computer -administered treatment condition and those receiving TAU. We expect participants in both experimental conditions to report a high level of satisfaction with the treatment modalities.*

Design and Methods Overview. We will implement this study within the current processes of care employed in Palo Alto's GMC (i.e., primary care).The current procedure for seeing patients in VAPAHCS primary care consists of the following. Patients check in at a front desk and then are asked to sit in a waiting room until a nurse is ready to bring them back to their physician's office. Once a patient has been called back to the exam room, the nurse completes a computerized version of the Health Habits Screening Worksheet (HHSW) (if it is due) which is an assessment that each patient completes once per year. The HHSW contains questions assessing unhealthy behaviors ranging from driving safety (e.g. "do you wear a seatbelt at all times while driving or riding in a vehicle?") to alcohol use ("have you had any alcohol containing beverages in the past 12 months?"). The HHSW contains all the items from the AUDIT-C. The VA currently uses a score of 5 or greater on the AUDIT-C to define the alcohol misusing patient population (Bradley et al., 2006); therefore, we will also use this criterion in our study. Patients who score a 5 or greater (and who are not currently seeking treatment for a substance use disorder) will be asked if they would like to participate in a research study that is focused on helping patients better understand how alcohol use may impact their life. The study nurses will recruit patients two - three days a week and will approach all patients who score 5 or above, except those who are missed while the nurse is providing feedback to other participants. *Patients agreeing to participate will be consented and randomized blindly to one of the three conditions – nurse or computerized feedback, or TAU.* Once randomized, patients in the experimental conditions will complete their physician visit before completing a baseline assessment and brief intervention. Once patients have completed their physician visit, they will be asked to proceed to the "patient kiosk" (containing a laptop computer and printer) to complete a brief assessment battery and print out an individualized feedback report that they will either take to their nurse or review themselves.

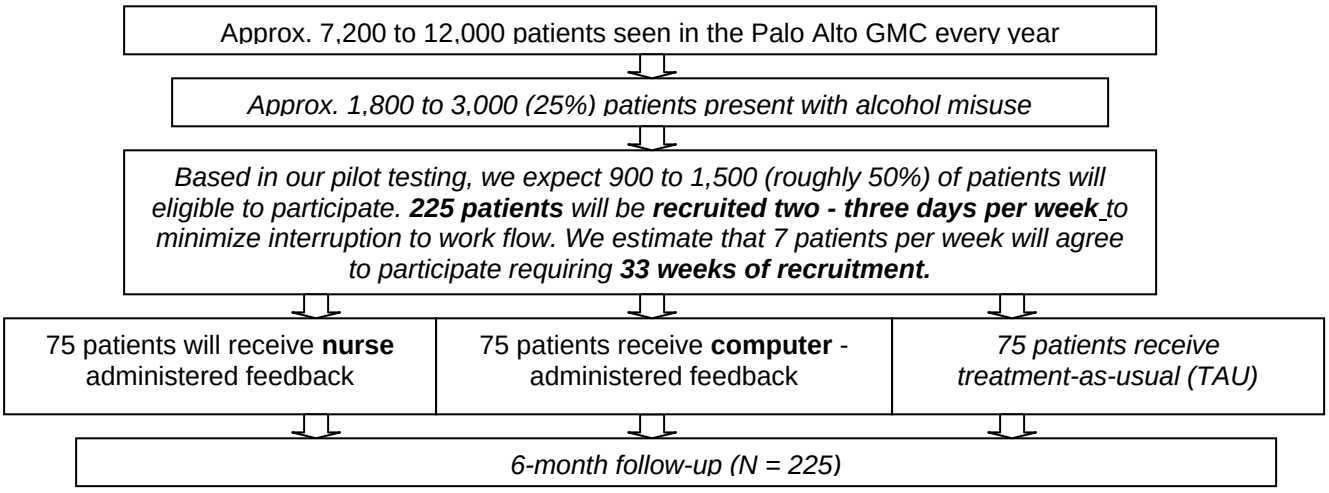
Computerized Assessment. *Upon completion of the baseline assessment questionnaires, patients in the experimental (computer- and nurse - administered) conditions* will complete a brief assessment of their use of alcohol, health risk factors associated with their alcohol use (e.g., "do you have hepatitis?" "do you have diabetes?"), their willingness to change their use of alcohol (e.g., on a scale of 1-10, how important is it for you to change in your use of alcohol?), and any negative consequences of their alcohol use (e.g., "I have had money problems because of my drinking" – true or false) using the patient kiosk located in the waiting room of the GMC clinic at the Palo Alto VA. Prior pilot work has demonstrated that the feedback portion of our assessment and feedback tool (AFT) takes 5-10 minutes to complete (Weingardt & Wilbourne, 2007).

Personalized Feedback Report. *Once patients in the experimental conditions complete the assessment portion of the AFT, an individualized feedback report is generated for them to print out and keep.* One group will take their report to a nurse for feedback, while the other group will be asked by research staff to review the report on their own. Research staff will be responsible for guiding participants through the study protocol including making sure patients print out the feedback report, paging nurses, and answering any patient questions. The personalized feedback report was developed using the principles of motivational interviewing and consists of the following elements – a summary report of patients' weekly use of alcohol and/or other substances; normative feedback on their alcohol use with respect to their age-matched peers; estimates of the consequences of their alcohol use on their health, finances, and time spent "under the influence"; a chart indicating their peak blood alcohol content (BAC) on a day within the past 90 days when they drank the most; psychoeducation on the physiological effects of various BAC values and factors that increase/decrease BAC; social consequences of alcohol and other substance use; any reported risk factors for increasing the social/health consequences of misusing alcohol; and a summary of their self-reported motivation to change.

Treatment-as-Usual (TAU). *TAU typically consists of two components - some form of explicit advice regarding recommended drinking limits, and a brief discussion with patients' on how their*

alcohol use may impact their health (Kivlahan, 2008). TAU can be provided by any licensed independent practitioner (e.g., physician, social worker, nurse, and psychologist). Participants in this condition will not receive the computerized assessment and personalized feedback report provided in the two experimental conditions.

Figure 1. Study Schematic and Patient Flow



Patients in the computer-administered feedback condition will be asked to read the feedback report on their own, while patients in the nurse-administered feedback condition will be asked to wait momentarily while a nurse is paged, by the RA, to go over their individualized feedback report with them. Nurses will review the feedback form with the veteran in an MI consistent manner which takes approximately 5-10 minutes (see Personalized Feedback Report above). Participants in the experimental conditions will be allowed to take their feedback report home for further review. We then plan to follow-up with patients in 6-months to assess primary and secondary outcomes.

Objective 2:

Examine the impact of these two interventions on veteran health care utilization at 6-months post treatment. *The second objective of study 1 (phase one) will be to examine the impact of all three interventions on veterans' health care utilization within the VA system.* Previous studies investigating the impact of brief interventions for alcohol misuse on health care utilization have had conflicting results – some studies show reduction in medical care utilization associated with brief interventions, while others do not (see Bray et al., 2007; Fleming et al., 2000; Freeborn et al., 2000; Storer, 2003). *Therefore, we hypothesize that:*

Hypothesis 1: Patients in both experimental conditions will demonstrate greater reductions in total VA health care utilization when compared to participants in the TAU condition, and this effect will be greater in the nurse -administered condition. *Previous* research shows that brief, motivational interventions are effective for reducing alcohol quantity and frequency in primary care patients (Senft et al., 1997) and that these reductions can result in decreased health care utilization (Holder, 1987). Studies finding reduction in health care utilization post-treatment have utilized health care providers as interventionists (Fleming et al., 2000; Storer, 2003), with no studies directly examining the impact of a brief, computer administered intervention for alcohol misuse on health care utilization*. We predict that computer -administered interventions will have a similar impact on health care utilization to nurse-administered interventions. Thus, we hypothesize that participants in both experimental conditions will show significantly greater reductions in VA health care utilization at 6-months post treatment when compared to those in the TAU condition. However, we also expect this result to be greater in the nurse-administered condition.*

Hypothesis 2: Patients receiving care in the nurse-administered treatment intervention will show greater reductions in health care utilization associated with acute rather than chronic alcohol misuse when compared to patients in the computer-administered and/or TAU conditions. Research shows that patients treated for alcohol misuse demonstrate greater reductions in medical care associated with acute medical conditions and accidents (e.g., fractures, sprain/strain, and open wound) attributed to active drinking and less of an impact on medical care usage associated with chronic alcohol misuse (e.g., cirrhosis, chronic pancreatitis) (Kane et al., 2004). *Given the hypothesized combined effect of the nurse-administered condition (patients will receive both paper and verbal feedback), we expect patients in this condition to report greater reductions in acute VA care usage at 6-months follow-up when compared to the other two conditions. We do not expect to see reduction in VA medical care associated with chronic alcohol use in any of the three conditions.*

Design and Methods Overview*. We will compare VA health care utilization data for all veteran participants for a period of one year 6-months prior to treatment to 6-months post-treatment. We* plan to collect several types of utilization data, including outpatient (e.g., mean number of mental health, primary care, acute care visits), inpatient (e.g., mean number of emergency room visits and extended hospital stays), and pharmacy utilization. We also plan to calculate total dollars spent for each type of health care utilization for the six months prior to treatment and 6-months post treatment using DSS cost data. Data will be collected using VA National Databases that track outpatient, inpatient, long-term care, and pharmacy utilization for patients in the VA health care system.

Description of VA National Databases. *The VA has developed files with information on every outpatient and inpatient (acute, long-term, and residential) encounter. The data are housed at the Austin Information Technology Center (AITC), with copies available on a Unix platform at CHCE. The files include ICD-9-CM diagnostic codes, CPT and ICD-9 procedure codes, and outpatient clinic identifier (stop code), as well as demographic information. A separate AITC file reports mortality data for VA patients. These databases have been used extensively in HSR&D research projects (e.g., Bradley et al., 2006; Seal et al., 2007).*

We will draw data from several of these national databases, including the Patient Treatment File (PTF) for inpatient services, the Outpatient Care file (OPC), and the Decision Support System (DSS) National Data Extracts. PTF and OPC feature diagnosis and procedure codes but lack costs or outpatient pharmacy information. DSS NDEs contain costs for every encounter and have detailed prescription-level information on inpatient and outpatient pharmacy. Thorough documentation is available for each of these datasets, and they have been used extensively in VA research such as those projects conducted in VA Centers of Excellence and the Health Economics Resource Center (e.g, Carey et al., 2008; Liu et al., 2008; Smith & Joseph, 2003).

Study Population, Inclusion / Exclusion Criteria, and Study Setting. *All veterans in VA primary care are supposed to be screened once per year. Veterans presenting to VA primary care who screen positive on the AUDIT-C for alcohol misuse will be approached about participating in the study. Exclusion criteria include current treatment for a substance use disorder, insufficient English language skills, and refusal to agree to follow-up telephone calls. Recruitment will take place in the General Medicine Clinic (GMC) on the main campus of the VA Palo Alto. Nurse participants will also be recruited from the VA Palo Alto's GMC clinic. As in Pilot Study 3, all nurses will be invited to participate. There are no other inclusion or exclusion criteria for nurses.*

Assessments

(a) Demographics - characteristic such as age, sex, BMI, and drinking habits will be collected at baseline. These variables are collected, in part, so that the computer program is able to estimate the blood alcohol content for each patient. *We assess possible exposure to various forms of substance abuse treatment during the 6-month follow-up assessment.*

(b) Patient satisfaction. We will use a 10-item patient satisfaction survey to assess patients' satisfaction with both methods of treatment delivery. This assessment was developed for Pilot Study 3 and will be used in the clinical trial. Patients will complete this assessment one time - immediately after receiving either intervention.

Primary Outcomes:

(c) Quantity and frequency of alcohol use. *The primary outcomes will be quantity and frequency of alcohol use. This will be measured using the 30 day, self-report version of the Time Line Follow-Back instrument (TLFB; Sobell & Sobell, 1992). The TLFB is a calendar of 1-3 months that provides visual cues to aid persons in retrospective recall of behavior. It uses "cues" (e.g., holidays, birthdays) to help a participant recall drinking behavior and has been shown to be reliable and accurate when given individually over the telephone or when administered by a computer program (Sobell et al., 1996).*

Secondary Outcomes:

(d) Situational confidence in identifying relapse cues. Situational confidence refers how confident a client is that he/she will be able to resist drinking when he/she encounters various high-risk relapse cues. This study will use the 8-item Brief Situational Confidence Questionnaire for alcohol (BSCQ; Breslin, Sobell, Sobell & Agrawal, 2000) to assess patients' ability to resist high risk relapse situations/cues. The BSCQ has well established validity.

(e) Consequences of alcohol use. *The Short Index of Problems (SIP) is a brief, 15-item version of the Drinker Inventory of Consequences (DrInC) which assesses alcohol-related problems in the alcohol misusing patients (Woolard et al., 2004). The SIP has been shown to have sound psychometric properties (Kenna et al., 2005).*

(f) Symptoms of psychological distress. Symptoms of psychological distress will be measured using the Brief Symptoms Inventory (BSI). The BSI instrument provides an overview of a patient's symptoms and their intensity at a specific point in time (Derogatis & Melisaratos, 1983). The reliability, validity, and utility of the BSI instrument are well established.

(g) Health status and Health-related quality of life. *The Short Form-36 for Veterans (SF-36V; Kazis, 1999) is an adapted form of the Medical Outcomes Study Short Form-36 which is designed to be used specifically with veterans. The measure, consisting of the same eight sections as the MOS SF-36, is used to assess health status. These sections are: physical functioning (PF), role limitations due to physical problems (RP), bodily pain (BP), general health perceptions (GH), energy/vitality (V), social functioning (SF), role limitations due to emotional problems (RE), and mental health (MH). The SF-36V is used widely by the VA and has demonstrated strong internal consistency. The SF-6D will allow us to calculate quality adjusted life years (QALYs) from the SF-36 for use in cost effectiveness analysis.*

Data Collection. Baseline patient assessment batteries will be administered via a secure web-based surveying software platform (http://www.vovici.com/) accessed in VA primary care. Patients will complete the 6-month follow-up assessment by telephone interview to be conducted by a research assistant. The main concern with patient self-report data is to ensure the accuracy and timely collection of such data for all participants. Other potential problems associated with the collection of patient self-report data include concerns about disclosing ongoing substance use, concerns about disclosing psychiatric symptoms, and concerns about jeopardizing their relationship with their physician (and other providers). Patients will be assured during the consent process that all assessment information (other than the initial AUDIT-C score which is part of their primary care visit) will be kept strictly confidential by research staff and will in no way impact the care that they receive.

6-Month Follow-up. *We plan to conduct a 6-month follow-up on all patients participating in the study. We will collect post-treatment data on all primary and secondary outcome measures including – alcohol use and frequency, situational confidence in identifying at risk cues, consequences of alcohol use, psychological distress, and health-related quality of life. A recent review of studies investigating the effectiveness of brief, motivational interventions for alcohol*

misuse found that 77% (17/22) of the studies conducted a follow-up at 3 months post-treatment in which case the authors highlighted the need for a longer follow-up period (see Vasilaki et al., 2006). Thus, study 1 (phase one and two) will build on this literature by extending the follow-up period to 6- months. Follow-ups will be conducted by telephone interview. We estimate that each phone interview will take approximately 20-30 minutes. Phone interviews will be conducted by a CHCE research assistant (RA) and volunteer practicum students (*blind to study condition)* from Stanford University and Pacific Graduate School of Psychology. Patients will be informed during initial consent that they will receive a $25 Super Certificate upon completion of the phone interview. Super certificates are gift cards that allow patients to redeem gift cards at multiple stores (purchased from www.giftcertificates.com). *The director of CHCE, Dr. John Finney, has agreed to provide funding for all 6- month patient follow-ups (see letter of support by Dr. Finney).*

Data Analysis Strategy (Objective 1). *To evaluate hypotheses of objective 1, we will conduct an Analyses of Covariance (ANCOVA) comparing the nurse- and computer-administered feedback conditions on each of the continuously measured outcome variables from baseline to 6-months after treatment. We will covary previous treatment for substance abuse, years of substance abuse, age, baseline AUDIT-C scores, and any other variable found to differ significantly between the two groups prior to entering treatment. We will also covary exposure to substance abuse treatment during the follow-up interval period to ensure observed treatment differences are due to the interventions themselves and not this factor. We will rely on tests of significance corrected for number of statistical tests (e.g., Bonferroni correction) and effect size to determine meaningful differences between groups. We also will conduct secondary ANCOVA comparing the three groups on each of the outcome variables at baseline. This secondary analysis will provide a gauge of the differences in alcohol quantity and frequency, situational confidence in identifying at risk cues, severity of alcohol dependence, and psychological distress prior to receiving treatment (Field, 2000). We will also compare baseline satisfaction scores for veteran participants in both experimental condition using a one-way ANOVA.*

Data Analysis Strategy (Objective 2): *We will use a difference-in-difference analysis appropriate for pre-post, repeated measures study designs to help control for confounding factors (Bray et al., 2007). This approach is similar to repeated measures ANOVA in that it provides both within and between groups comparisons using means of outcomes of interest (e.g., mean number of selected outpatient, inpatient, and pharmacy utilization types) for the two treatment conditions. We will also adjust for other factors that contribute to utilization of health care services such as age and the presence of a chronic disease(s). Difference-in-difference analysis calculates the difference in means for all outcomes of interest between the two groups pre and post treatment, and then calculates the difference between these two values for a difference-in-difference value. This analysis also provides 95% confidence intervals for each of these values. The PI will conduct all statistical analyses for study 1 (phase one and two) while receiving consultation from Drs. Sox-Harris and Smith respectively.*

Missing Data. *The interview format of the baseline and follow-up assessments, and the flexibility of the interviewers to schedule calls at patients' convenience, will help to reduce missing data. To maximize the number of observations available for analysis, we will utilize a multiple imputation strategy to impute missing data values. Multiple imputation predicts missing values so that an intent-to-treat analysis can be performed on patients who might otherwise be dropped from the study due to incomplete data. Multiple imputation has been shown to be the preferred to method for handling missing data in treatment outcomes studies (Schafer & Chinchilli, 2007).*

Statistical Power. *We will have more than adequate power to test the hypotheses of objectives 1 and 2. Using results of previous research (reduction in alcohol quantity and frequency, and reductions in acute care utilization); we estimate a small to medium effect size (i.e., .1 to .3) for both treatment conditions (to detect both within and between group changes). A power analysis*

was also conducted to determine the sample size necessary to find an effect using a power of 80%. We determined that a sample size of 192 (n = 64 for each of the three conditions) veterans patients is needed to find an effect if one is present. Previous research (e.g., Senft et al., 1997) has also found an approximately 16% attrition rate among adults participating in brief alcohol counseling in primary care medicine. To correct for possible attrition, we have added an additional 33 veterans to the study (an additional of approximately 16%) for a total of 225.

Potential Limitations. *Study 1 (phase one and two) will be designed as randomized, controlled trials. There are number of potential limitations associated with this approach including (a) insufficient power to detect a treatment effect when one is present; (b) inadequate randomization processes; and (c) failure to blind treatment providers and/or assessors to the hypotheses being examined (Stolberg, Norman, & Trop, 2004). We have attempted to minimize the impact of limitation A by conducting an a priori power analysis (see above) using the existing literature to estimate treatment effects. To ensure appropriate randomization we will randomly assign patients to one of the three treatment arms through the SPSS statistical software application. Regarding limitation C, nurse participants will not be explicitly told the hypotheses under study. However, they will be informed that we are conducting a study to examine the impact of two methods for delivering a brief, motivational intervention for treating alcohol misuse in VA primary care. We believe that these remedies will address the aforementioned limitations thus muting their effect on the present studies.*

Study 1 (phase two)

Objective: ***Examine the cost-effectiveness of each intervention relative to TAU and each other.*** *The next step in this program of research is to use data collected from study 1 (phase one) combined with administrative data collected from national VA databases to examine the relative cost-effectiveness of both interventions. Cost-effectiveness analysis is important when considering adopting new clinical practices because resources are scarce and choices must be made among competing alternatives (Cucciare & O'Donohue, 2005a; Drummond et al., 2001; Yates, 1999). Health administrators report that they take cost-effectiveness into account when making important decisions about which interventions to implement (Bloom 2004).*

Study Hypotheses. *We have two main hypotheses for Study 3.*

Hypothesis 1: Both experimental treatment conditions will be cost-effective relative to TAU. *Research supports the cost-effectiveness of brief interventions for alcohol misuse in terms of reductions in medical and societal costs (Mundt, 2006). In addition, a recent literature review concluded that brief interventions for alcohol misuse are a wise use of economic resources (Kraemer, 2007). Therefore, we hypothesize that both experimental interventions will prove to be cost-effective (i.e., more effective in relation to their costs) relative to TAU. We will use cost effectiveness ratios to consider both (a) the resources necessary to implement the three interventions and (b) their impact on patient outcomes and certain types (e.g., acute care) of VA medical care utilization.*

Hypothesis 2: The nurse-administered feedback condition will be cost-effective relative to the computer-administered condition. *There is a lack of research directly comparing the cost-effectiveness of computer- and nurse-administered brief interventions for alcohol misuse. However, research shows that provider administered brief interventions for alcohol misuse can result in considerable savings in medical (acute care) care utilization (Holder, 1987). We hypothesize that the addition of a nurse to help patients interpret the results of their feedback report may lead to greater overall impact on the primary and secondary outcomes, resulting in a potential reduction in certain types (acute care) medical care usage. Therefore, we expect the nurse-administered condition to show greater cost effectiveness when compared other two conditions.*

Design and Methods Overview*. Data gathered from study 1 (phase one), VA national databases, and existing cost data (collected by the developer of the AFT - Dr. Weingardt)*

associated with implementing the computer-based intervention tool will be used to test the hypotheses of study 1 (phase two). For data that are not located within the VA (e.g., direct program costs), we will use the methods described by Rosenheck & Frisman (1995) to estimate the costs associated with both experimental interventions and TAU. Specifically, Rosenheck & Frisman describe methods for estimating (a) direct program costs (e.g., rental space, staff salary and training costs); (b) indirect costs (e.g., administrative costs associated with delivering mental health interventions); and (c) program resource costs (e.g., purchasing computer and printer equipment, software development). Costs under (a) and (b) will be estimated using national VA administrative data. Purchase costs under (c) will be estimated from purchase records at the Palo Alto VA. The cost of staff time under (c) will be based on HERC estimates of national average staff costs (King & Smith 2007). I will work closely with Dr. Smith (HERC) to develop and analyze the above data to arrive at cost estimates for each intervention.

Data Analysis Strategy. *Cost-effectiveness ratios (CE ratio) will be used to examine both hypotheses (see Drummond et al., 2001). CE ratios take into account the costs associated with both delivery methods relative to their impact on outcomes of interest. CE ratios will be used to perform pre-post and difference-in-difference analyses. The average cost for clinical outcome (such as cost for a 1 drink-per-day reduction) will be computed for each arm from baseline to 6-month follow-up. We will then compare this average cost across arms (nurse vs. TAU, computer vs. TAU, and nurse vs. computer), and the numerator be the difference in cost per patient between the two arms being compared. The denominator will be the difference in clinical outcome. For all analyses we will use an appropriate method, such as bootstrapping, to develop standard errors and thereby to determine statistical significance.*

Study 2

Objective: To extend the findings of study 1 (phase one and two) by conducting a multi-site RCT to examine the relative (cost) effectiveness of both experimental conditions and a TAU control group. *If the hypotheses stated in study 1 (phase one and two) are supported by the trial results, we will then examine the relative effectiveness of all three interventions at multiple VA primary care sites within VISN 21. We will select three VA primary care sites that report the most difficulty completing follow-ups on patients with positive screens. These data will be located through the External Peer Review Program. To fund this study, I will simultaneously submit two grant applications in year three (June) of my CDA award: a VA investigator-initiated research (IIR) project and an NIH RO1. During the six months leading up to these grant submissions, I will work closely with my mentors and Dr. Rudy Moos on my grantsmanship and provide them with multiple drafts of these two grant applications to obtain feedback. I anticipate starting this multisite trial at the end of the fourth year of my CDA award, or during my transition from my CDA to becoming an independently funded health services researcher (depending on when funding begins). While I purse funding for this project, I will also work simultaneously on several secondary research activities which are described below.*

Should this multi-site RCT provide evidence for the effectiveness of brief, motivational interventions for treating alcohol misuse in three VISN 21 primary care sites, I plan to continue this line of research in the form of an implementation study. Using methods outlined by the VA Mental Health QUERI (Curran, Mukherjee, Allee, & Owen, 2008), I plan to conduct a third study to examine the most effective methods for implementing the evidence-based practice(s) identified in study 1 (phase one and two) and study 2 within the VA system. To fund this implementation project (i.e., study 3), I plan to submit a VA HSR&D IIR and NIH RO1 during the second or third year of transition into an independently funded health services researcher.

Alternate Study 2

In the event that we observe no statistically significant differences between the three treatment (or two experimental) conditions, I plan to reexamine the effectiveness of the two

experimental treatments (using an RCT) after adding components to the treatment. For example, my mentors (and Dr. Moos) and I have discussed the possibility that a single, brief intervention session may not be effective for reducing our primary outcome (alcohol use and frequency). If this result were to occur, the next phase of this research program would consist of adding a "booster" session (or sessions) to the two interventions. These additional sessions could be delivered by a nurse or behavioral health care provider in-person or by telephone in weeks following the initial session.

Secondary Research Activities

Study 3

I plan to write a literature review synthesizing empirical evidence for using brief screens and mental health treatments to treat alcohol and drug misuse in primary care medicine. This manuscript will focus on elucidating how brief screens and interventions might be implemented, various procedures that can be used (e.g., in person v. computer-based), and the extent to which they are effective for impacting various outcomes (e.g., reduction or abstinence of a substance). I plan to begin conducting research for this project in the third year of my CDA award. A draft of this paper will also be used as part of the literature review for the IIR and RO1 grant proposal planned for year three of my CDA award.

Study 4

I plan to work with Dr. Weingardt (Principal Investigator) on a study funded by the National Institute on Drug Abuse to examine two methods for training mental health providers in cognitive behavioral therapy (CBT). The study proposes randomly assigning 300 community mental health providers to a "low" and "high" fidelity web-based training. Training lasts one month and consists of several web-based components such as online didactic and supervision session. Data are being collected at baseline, one and six-months following training. Primary outcomes include providers' level of CBT knowledge, self-efficacy, and work-related burnout. I plan to work with Dr. Weingardt on conducting the statistical analysis of these outcomes and preparing two manuscripts for publication – one to report training outcomes, and one to report predictors of providers' response to training. These projects will help me develop expertise in using computer-based strategies to train providers in EBPs more broadly (such as CBT), conducting statistical analyses on treatment outcomes, and experience in authoring empirically-based manuscripts.

Study 5

I plan to collaborate with Dr. Jodie Trafton (a CHCE core investigator) on a study investigating predictors of response to CBT treatment in a sample of HIV-positive patients reporting comorbid pain and alcohol misuse. This study consists of integrating a 12-week CBT intervention into a primary care clinic specializing in providing acute care to HIV positive patients. Primary outcomes include various aspects of pain-related functioning, and alcohol use and frequency. Data are being collected at baseline, post-treatment, and 24 week follow-up. Along with resubmitting grant proposals to fund study 2 or conducting pilot work on alternate study 2, I plan to work with Dr. Trafton on this project in year 4 of my CDA award. My roles will include conducting literature reviews, statistical analysis (e.g., linear and logistic regression) and interpretation, as well as preparing the results for publication. This project will help me develop expertise in factors that are predictive of mental health treatment success in a comorbid sample of patients seeking treatment in a primary care setting. Identifying predictors of treatment success is particularly relevant to my fourth training goal (to develop expertise in the implementation of EBPs in primary care medicine) as this research activity will help me further develop an understanding for whom EBPs such as CBT tends to be most beneficial. This secondary research activity will also provide me with much needed experience preparing empirically-based manuscripts.

HUMAN SUBJECTS

A. Risk to Subjects.

A. 1. Human subjects involvement and characteristics. Two participant samples will be involved in this study – nurse and veteran (or patient) participants. Nurse participants will be recruited to participate in a web-based training program for learning a motivational-based intervention for treating veterans presenting to VA primary care with alcohol misuse. *Nurses will receive training in a motivational intervention and asked to participate in a weekly phone supervision meeting with the PI. Veteran participants will be recruited to participate in randomly assigned study comparing the relative effectiveness of two methods for delivering a brief, motivational intervention for treating alcohol misuse and a TAU condition.* Veterans will be recruited from a VA primary care clinic (General Medical Clinic or GMC) at VA Palo Alto. Inclusion and Exclusion Criteria. The sample will be drawn from a population of veterans who currently receive VA primary care services. *Specifically, veterans presenting to VA primary care who screen positive on the AUDIT-C for alcohol misuse will be recruited for the study. Criteria for inclusion in the study includes being eligible for AUDIT-C screening (veterans are screened once per year), screening positive for alcohol misuse, and not presently in treatment for a substance use disorder. Patients will be asked by trained nursing staff whether they are currently seeking treatment for a substance use disorder.* The study will be conducted in the General Medicine Clinic (GMC) located in Palo Alto, CA. At present time, this clinic sees approximately 30-60 veterans per day and research shows that approximately 25% of these patients screen positive for alcohol misuse. Nurse participants will be recruited from the VA Palo Alto's GMC clinic. As in the case of Pilot Study 3, all nurses will be invited to participate (there are no specific eligibility requirements other than being a nurse).

Veteran Participant Characteristics. We plan to recruit 225 alcohol-misusing veterans to participate in this study. All veterans will be recruited from VA primary care. Past research shows that samples of alcohol-misusing veterans have a mean age of 60 years, with 70% identifying as Caucasian, 10% African American, and 18% as other. Most report that they are married/widowed (44%) or separated/divorced (43%), and have an income of less than $20,000 (68%). This population of veterans also reports a high degree of medical comorbidity with hypertension (54%), COPD (25%), diabetes (19%), coronary artery disease (13%), liver disease (9%), and other drug abuse (7%) (Bradley, et al., 2002). Nurse Participant Characteristics. We plan to recruit 3-5 additional nurses from the GMC to receive training in our web-based course. Approximately 10-15 nurses are employed in this clinic with various educational backgrounds (e.g., nurse practitioners, licensed vocational nurses, registered nurses).

A. 2. Sources of Materials. Data will be gathered from veteran participants in two forms. First, self-report data will be gathered for research purposes during the course of studies 1a. Screening for alcohol misuse is a standard procedure in the VA GMC and is conducted for all veterans. We will use this data to determine eligibility for the study (i.e., a score of 5 or greater is required for eligibility). Second, health care utilization will be drawn from an archival VA data source in which participants are identified only by scrambled SSNs. These data were collected as part of routine clinical care within VA facilities nationally and centrally compiled into the DSS registry. These data were not collected as part of a specific research protocol such as the proposed study, but can be utilized for such scientific endeavors. A linkage file between the participants' medical records and the data exists as participants are centrally assigned a unique identification number (which is scrambled).

A. 3. Potential Risks. The risks associated with participating in this study are low and will be minimized by several factors. First, as with any study, there is a small risk of breach of confidentiality since all participants will be disclosing personal health information. However, all patient and nurse self-report data will be de-identified, kept securely in locked facilities, and held in accordance with current VA regulations and standards. Second, although not expected, it is

possible that a patient could have a negative emotional reaction to discussing his or her alcohol use. As with all participants, any patient reporting a negative emotional reaction would be advised that they are free to withdrawal from participation at any time. They are also free to use any of the mental health services available within the VA to discuss these reactions. All adverse negative reactions will be reported to both VA R&D Office and Stanford University Human Subjects.

B. Adequacy of Protection from Risks

B. 1. Recruitment and Informed Consent. The proposed studies use both patient and nurse self-report and patient archival data. Therefore, consent will be obtained from nurses and patients. Nurse participants will be recruited from the VA Palo Alto GMC clinic*. The nurse clinical coordinator, David Renfro, RN, MS, will send an email to all nurses to determine interest in participating. Interested nurses will then be asked to contact the PI to complete the informed consent process.* Once consent is received, nurse participants will be given the course on CD-ROM and pre/post knowledge test. Veteran participants will be recruited from a primary care setting located in the GMC clinic at the Palo Alto VA. Currently, nurses working in this setting are required to screen all patients using the AUDIT-C, which is a screening tool that is helpful for identifying patients who are engaging in alcohol misuse. Participation will involve the following procedure: (a) the screening nurse will assess alcohol use using the AUDIT-C which is currently part of the intake process in the GMC clinic at PAD, (b) patients who screen positive (i.e., a score 5 or more) will be asked (by the screening nurse) if they would like to participate in a research study that is "focused on helping patients better understand how alcohol use may impact their life." Patients who agree to participate will be provided two copies of the consent form - one for them to sign and return to the investigator and one for their records.

B. 2. Protection Against Risk. Several efforts will be made to minimize any potential risk associated with participation in this study. First, in order to minimize the risk of loss of confidentiality and privacy, all data will be collected by research staff for research purposes only and will be stored in locked files on password protected computers with only code numbers identifying participants. Participant information will be accessed only by research staff. Identifying information will not be reported. Other potential problems associated with the collection of patient self-report data include concerns about disclosing ongoing substance use, concerns about disclosing psychiatric symptoms, and concerns about jeopardizing their relationship with their physician (and other providers). All of these concerns will be addressed with patients, along with the steps we are taking to ensure the strict confidentiality of their data and the fact that patients' research participation or non participation will have no effect on the regular health care they receive. The use of a secure, password-protected web data entry mechanism entirely excludes providers from the data collection process, which should help clients to feel more comfortable disclosing sensitive information. Second, in order to protect patients from emotional distress due to the clinical assessments, all assessments will be administered by trained clinical assessors with experience conducting such assessments with veterans. Furthermore, the PI on the proposed project has a Ph.D. in clinical psychology with training and experience in psychological assessment and treatment. Minor difficulties (e.g., emotional distress) will be sensitively handled by the clinical assessor and referred to VA mental health services when appropriate (but not expected). Although there is no basis to expect that the proposed clinical assessment will elicit major emotional distress (i.e., suicidality), if patients report any serious such adverse events during the course of clinical assessment, they will be walked over by staff to the emergency mental health services located on PAD campus. Third, as an additional protection against emotional distress secondary to study participation, and as noted above participating patients will be informed verbally and in writing that they can withdraw from the study at any time without penalty to them.

C. Potential Benefits of the Proposed Research to the Subject and Others. The minimal risks described above are justifiable and reasonable in terms of benefits to the participants and

others who are expected to gain from the proposed research. First, veteran and nurse participants are expected to benefit from participation in a number of ways. Veteran participants are likely to demonstrate reductions in alcohol use and frequency by engaging in the brief intervention. We also anticipate that veterans in both experimental conditions will benefit from the intervention as demonstrated by their ability to manage situations that may serve to "trigger" the use of alcohol, and by a reduction in psychological distress that often accompanies alcohol misuse. Second, VA nurses are also expected to benefit from study participation. Training in brief, motivational interventions will likely decrease the potential for conflict with alcohol-misusing veterans, as nurses may rely less on direct confrontation and more on the discussing patients' reactions to the different aspects of feedback (e.g., normative comparisons of their alcohol use and financial, health, and relationship consequences). Brief, motivational interventions have been shown to be effective in helping patients change behaviors associated with a wide variety of other psychological (e.g., other drug use) and medical problems (e.g., diabetes, asthma, hypertension). Therefore, we expect that nurses will observe a benefit from the training in their general practice.

D. Importance of the Knowledge to be Gained. The studies proposed in this CDA application will support current VA National initiatives focused on implementing evidence-based brief alcohol counseling in VA primary care. The initial step in this initiative involved implementing a Nationwide Alcohol Misuse Screening Performance Measure (i.e., AUDIT-C) in primary care for alcohol misuse, which reliably identifies veterans engaging in alcohol misuse. In response to the large portion of veterans screening positive for alcohol misuse, the VA Office of Patient Care Services, VA researchers (e.g., Bradley, 2006), and the VA/HSR&D Substance Use Disorders Quality Enhancement Research Initiative have focused much recent effort on developing strategies for treating this population of veterans. The studies proposed in this application for a CDA-2 will support of these efforts. We hope to extend this VA patient care mission by evaluating two methods for delivering brief alcohol counseling in VA primary care. These studies may lead to important improvements in the manner in which alcohol misuse in treated in VA primary care.

ANIMAL STUDIES SECTION

Not Applicable

RESOURCES

The Center for Health Care Evaluation (CHCE) is located on the VA Palo Alto campus (in Menlo Park) and includes sufficient space and all necessary equipment to conduct the proposed research. For example, copiers, fax machines, scanners, and LCD projectors, are available to all researcher personnel. CHCE will also provide administrative support as well as access to print and office supplies. CHCE is well-equipped with office and computer supplies including office space with telephone, voice mail, e-mail, and personal computers and printers for all research personnel. Regarding computers and relevant technology, the CHCE has the following: a centralized server and mass data storage device that is fire-walled, encrypted, and backed-up daily; two information technology specialists to ensure data security and integrity; networked personal computers for all personnel; and statistical, publishing and database software for data management and analysis. Relevant to data storage and safety, CHCE has access to local Windows Active Directory Domain Controllers, a UNIX NIS Server and Network Appliance storage facilities. These resources allow large amounts of research data to be stored and analyzed within a secure environment, while still connected to VA computing resources. Network infrastructure and connectivity are maintained by the Shared Computer and Resources Facility (SCARF) that serves CHCE and the VA's Cooperative Studies Program Coordinating

Center (CSPCC), HERC, and the Program Evaluation and Resource Center. Additional hardware, software and support services are provided by the SCARF for the various projects and programs within the building. All the resources described in this section are available to the nominee.

LITERATURE CITATIONS FOR NARRATIVE

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