

Identifiers: NCT03258632 Unique Protocol ID: IIR 15-298

Brief Title: Improving Outcomes Among Medical/Surgical Inpatients With Alcohol Use Disorders

**IIR 15-298**

**Improving Outcomes among Medical/Surgical Inpatients with Alcohol Use Disorders**

Christine Timko PhD and Mark A Ilgen PhD

VA Palo Alto Health Care System, Palo Alto, CA; VA Ann Arbor Health Care System, Ann Arbor, MI

Last update/approval: February 1, 2022

## **02a. Research Plan: A. Background and Significance**

**A.1 AUDs are common in medical-surgical inpatients.** About 24%-36% of persons admitted to general hospitals have AUDs or are being treated for drinking consequences.<sup>6,7</sup> Over 75% of medical inpatients who drink risky amounts of alcohol are alcohol-dependent.<sup>8</sup> In FY14, 57,281 Veterans receiving VHA inpatient medical-surgical services (excluding psychiatry and addiction treatment settings) had diagnosed AUDs in the medical record.<sup>1</sup> This likely underrepresents the prevalence of AUDs among Veteran medical-surgical inpatients because these disorders often go undiagnosed during hospital stays.<sup>2</sup>

**A.2 AUDs and medical conditions are interrelated.** Three primary pathways explain how AUDs contribute to poorer outcomes in treated medical conditions.<sup>3</sup> First, AUDs may be a causal factor in the development of a medical condition. Alcohol use is a common cause of liver disease, upper gastrointestinal (GI) bleeding, and pancreatitis.<sup>9</sup> Among Veterans, more severe AUDs were associated with increased risk of GI<sup>10</sup> and traumatic injury<sup>11</sup> hospitalizations. Secondly, AUDs may exacerbate health conditions that developed apart from drinking, such as diabetes. Large amounts of acute or long-term alcohol ingestion increase insulin resistance, triglyceride levels, blood pressure, and all-cause mortality.<sup>3</sup> Severe alcohol use was independently associated with poorer outcomes among patients with acute lung injury.<sup>12</sup> In the third pathway, AUDs complicate effective management of existing medical conditions. They are associated with poor illness control via poor adherence to diet, no-smoking, and physical activity recommendations and medications.<sup>13,14</sup> Findings underscore the importance of identifying and treating AUDs in medical-surgical inpatients to improve health.

**A.3 AUDs with medical-surgical conditions increase costly health services use.** Unhealthy alcohol use by surgical patients is common and linked to increased risk of complications. Among Veterans having major surgery, more severe drinking up to a year before, and immediately prior to, surgery, was associated with increased post-op complications and health care utilization, i.e., return to the operating room, longer post-op hospital length of stay, more intensive care unit days, hospital readmission.<sup>15,16</sup> Unhealthy alcohol use was also related to complications following total joint arthroplasty among Veterans.<sup>17</sup> In one study, medical inpatients were 1.6 times more likely to be readmitted within 30 days of discharge when they had an AUD than when they did not.<sup>7</sup> Alcohol-related complications are among the top four reasons for readmission.<sup>7</sup>

**A.4 Hospitalization is an opportunity to address AUDs.** Not only are AUDs common among medical-surgical inpatients, but the majority of medical-surgical inpatients with unhealthy alcohol use continue to drink and have negative alcohol-related outcomes following hospital discharge.<sup>18</sup> Hospitalization for medical problems represents a teachable moment to prevent the negative consequences of AUDs and an opportunity to conduct interventions to initiate addiction treatment when needed.<sup>19</sup> Intervening related to alcohol during a medical stay has the potential to facilitate treatment for AUDs by increasing recognition of the need to reduce drinking, intent to do so, and awareness that engaging in alcohol treatment post-hospitalization is needed to reduce drinking.<sup>18</sup> Brief Interventions (BIs; 1-2 counseling sessions of up to 30 minutes each, reviewing personalized feedback on normative comparisons of alcohol use, self-reported consequences of use, and motivation to change alcohol use) are effective for patients at risk of developing AUDs.<sup>3</sup> However, randomized trials have revealed that BIs lack efficacy, and consistent and sustained benefit, to alcohol, medical, and treatment utilization (initiation, engagement) outcomes among hospitalized patients with AUDs.<sup>6,20,21</sup> In addition, referrals to behavioral counseling or social services are insufficient to ensure safe discharge and treat AUDs among inpatients.<sup>7</sup> Overall, despite the potential promise of the inpatient setting for delivering AUD-focused BIs or simple treatment referrals, studies have not found compelling evidence for these approaches. One likely reason is the lack of a link between efforts to help patients realize that alcohol is problematic for them, with concrete and balanced discussions about realistic treatment options that fit with patients' preferences, combined with lack of support for AUD-specific goals following discharge.

A clear opportunity exists to develop and test new approaches to address the pressing need regarding AUD treatment in the context of inpatient medical-surgical care. In VA, only 4% of 10,384 ambulatory care patients with AUDIT-C scores of  $\geq 8$  (VHA guidelines recommend AUD treatment for all patients with an AUDIT-C score of  $\geq 8$ ) received addiction treatment in following year.<sup>22</sup> Among older medical inpatients with alcohol problems, only 18% attended a treatment placement evaluation session post-discharge;<sup>23</sup> of those attending the session, only 50% initiated treatment.<sup>24</sup> Yet, those who attended treatment had better 6-month drinking outcomes than those who did not.<sup>25</sup> Informing patients about the full menu of available evidence-based help options should increase the proportion of medical-surgical inpatients engaged in such help for their AUDs. In a pilot program at a private hospital, inpatients with hazardous or harmful alcohol use received assessment, Motivational Interviewing (MI), and facilitated referral to addiction treatment by a patient engagement specialist. These patients showed a 33%-58% (depending on the study cohort) pre-post decrease in inpatient medical admissions, a 13%-38% decrease in emergency visits, and an increase of 32%-42% in AUD treatment

initiation; 43% of patients entered AUD treatment after hospital discharge.<sup>26</sup> Similarly, implementation of a discharge planning protocol to improve the treatment of alcohol dependence with inpatients, consisting of MI to discuss alcohol use and treatment preferences, screening for naltrexone eligibility, providing prescriptions, and arranging follow-ups, found pre to post increases in naltrexone prescribing, and decreases in 30-day readmissions and emergency visits.<sup>7</sup> These small studies support an integrated motivational-decision aid-monitoring approach to bridging the gap in care for medical-AUD inpatients.

A.5 DO-MoST may improve outcomes. Having noted the lack of evidence-based strategies to improve AUD treatment utilization (initiation, engagement) and outcomes (less or no drinking; better health) among medical-surgical inpatients with AUDs, we hypothesize that VHA may benefit from a patient-centered approach in the real-world clinical situation of medical-surgical inpatients having inadequate treatment of their AUDs. This approach is “Drinking Options - Motivate, Shared Decisions, Telemonitor” (DO-MoST). We hypothesize (Figure 1) that DO-MoST, begun during the inpatient episode, will facilitate the transition to AUD help that is evidence-based (i.e., behavioral and/or pharmacological treatment, mutual-help groups) and improve outcomes.<sup>4,27</sup> DO-MoST has 3 components: 1. MI to motivate patients to change drinking and initiate help; 2. Use of a Decision Aid for patients to choose the type of evidence-based help they prefer and need; and 3. Telemonitoring (TM) to support and monitor patients’ initiation of and engagement in their preferred modality of help; or, for patients not motivated to change drinking and initiate help, TM to continue to engage in MI. MI is a patient-centered counseling approach for behavior change, used typically when patients feel ambivalent, allowing counselors to have goals for counseling while acknowledging and exploring variations in individuals’ commitment to, and interest in, changing behavior. MI has evidence of efficacy in treating addictions in other settings.<sup>28</sup>

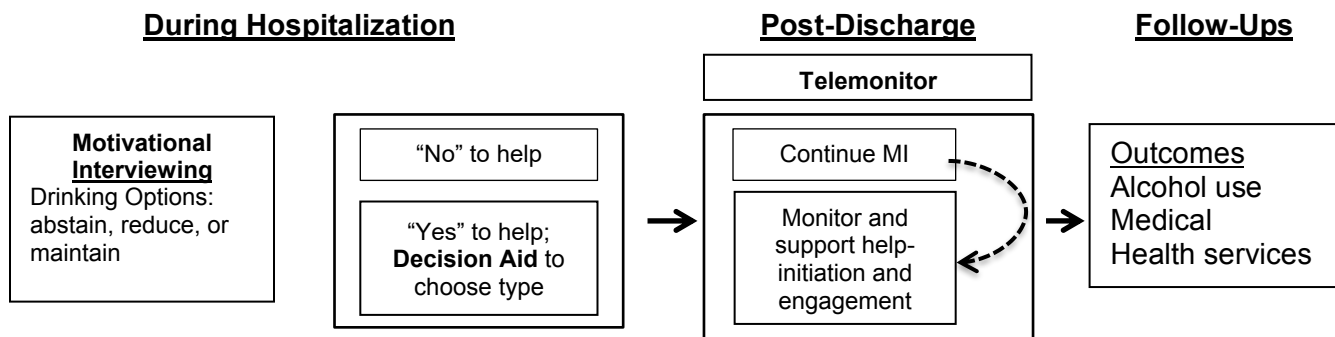


Figure 1. Conceptual model of Drinking Options - Motivate, Shared Decisions, Telemonitor (DO-MoST).

Do-MoST introduces the Decision Aid when MI has readied patients to make decisions about help. Decision aids have been used by providers and patients to make decisions together using the best available evidence; they encourage patients to consider available treatment options and the likely benefits and harms of each.<sup>29</sup> Providers, such as decision coaches (trained to support patient involvement in decisions), help patients become well-informed and develop personal preferences for available options, and offer professional guidance. Deciding about treatment options is a dynamic process, with information exchange between health care staff and patients. Historically, most Decision Aids have been employed in situations without a clear, “best” treatment option; instead, the goal is to help patients make decisions that are satisfying to them. In the case of medical-surgical inpatients with AUD, evidence is clear that outcomes would likely be better if the individual reduced alcohol consumption with treatment engagement. DO-MoST, capitalizing on patients’ motivation to change, will share this evidence with patients, but discussions will focus on choosing the help option that is best from the patient’s perspective. Existing empirically-based options for AUD include medication treatments (3 types: disulfiram, acamprosate, and naltrexone, approved by the FDA), behavioral treatments (4 types: cognitive-behavioral, motivational enhancement, behavioral couples, and twelve-step facilitation therapy, which are equivalent in terms of outcomes), and mutual-help groups. The goal of the Decision Aid component is to present AUD patients with the pros and cons of each option and engage them in a discussion of which option might be best for them if they choose to pursue some form of help.

A Decision Aid for AUD treatment may be particularly effective because individuals with AUD are often unaware of the range of available options in terms of treatment modality and outcomes. Even Veterans receiving detoxification and other psychiatry services for their substance use disorders are unaware of the range of evidence-based treatment options available for AUDs, such as pharmacotherapy or outpatient treatment.<sup>30</sup> Patients often believe that the 28-day residential treatment model is the main one available and recommended.<sup>31,32</sup> Further, patients often do not view providers as open to discussion of the goal of cutting

down rather than abstaining,<sup>33,34</sup> even though abstinence is not considered a desirable goal by large proportions (39%-53%) of alcohol-dependent treatment-seekers.<sup>35,36</sup> Patient-driven goals other than abstinence may help reduce alcohol-related harm and improve quality of life.<sup>37</sup> For patients with AUDs seen in medical-surgical inpatient settings, an intervention to increase engagement in evidence-based AUD help needs to, in addition to explicitly targeting motivation to change alcohol use and engage with resources for help, explicitly discuss treatment options in a decision aid approach and be monitored.

TM is needed to continue change processes begun during the in-person session with the Decision Coach. AUD is a chronic condition, often developed and existing over a long period, such that brief conversations during a hospitalization are unlikely to have sustained impact without follow-up reinforcement. Some inpatients with unhealthy alcohol use may be especially receptive to intervention when recovering from a medical illness. VA and non-VA medical-surgical inpatients are often accepting of discussing alcohol use during the stay.<sup>26,38-40</sup> However, other medical-surgical inpatients may see their hospitalization as unrelated to their history of alcohol use, view their unhealthy alcohol use as secondary to their current health concerns, or be distracted by these concerns, fatigued, or in pain. Even when inpatients welcome discussion of their alcohol use during hospitalization, perceived benefits of changing drinking by initiating help may fade. Insights from an inpatient intervention may not be learned or retained well enough to yield behavior change and help-initiation post-discharge. Inpatient interventions are often seen as necessitating continued discussions of alcohol use and help-initiation at later points, after the hospitalization has been resolved and patients are able to be more receptive. Such considerations have led to recommendations that multi-contact interventions be provided via phone.<sup>41</sup> Post-discharge TM reminds patients of the during-hospitalization discussion about alcohol use, encourages and reinforces commitment to change drinking, explores barriers patients may have encountered in changing drinking and initiating help, and reinforces putting help-initiation into action. This may be especially needed because there is often a delay from referral and/or intake, to entry, in many VA AUD treatment programs. In the planned study, for patients who do not want to change drinking or initiate help, TM serves the purpose of providing ongoing contact with a counselor during the post-hospitalization period. The MI-consistent stance of the Coach delivering TM will ensure that patients feel supported and know they can reach out to VA if and when they want further assistance reducing their drinking. Procedures will be conducted while avoiding any direct confrontation that would *build resistance or diminish participants' engagement in this type of care*.

Randomized trials have compared intervening with medical patients with unhealthy alcohol use using a one-time in-person session to address drinking, to the session plus subsequent "booster" sessions. Patients in booster conditions had significantly better alcohol outcomes than patients without boosters, e.g., reductions in alcohol-related negative consequences such as injuries. However, these studies were conducted mainly with hazardous or harmful drinkers.<sup>42</sup> Another study of medical inpatients identified as unhealthy alcohol users (including alcohol dependence) in Taiwan comparing UC to intervention (in-person session during hospitalization, plus up to 2 booster sessions), found that intervention patients had better 1-year alcohol outcomes (reduced consumption, drinking days, heavy drinking episodes), and that, within the intervention group, the more sessions attended, the more likely patients were to seek treatment and improve on alcohol outcomes.<sup>43</sup> Benefits of alcohol interventions during hospitalization are more likely to persist if interventions extend post-discharge. A systematic review of interventions for heavy drinking inpatients found that multi-session, but not single-session, BIs were associated with reduced drinking up to one year later.<sup>44</sup> In addition, telephone-monitored addiction patients were more likely to report abstinence on days they made calls than on those they did not, and less likely to increase on drinking days per week than controls.<sup>45,46</sup> Post-discharge monitoring sessions for 3 months are well-attended by patients and associated with better substance use outcomes partly via patients' greater self-efficacy for avoiding substance use in the monitoring condition that offers cumulative support and encouragement.<sup>47</sup> The number of monitoring sessions for the present study is designed to enhance the intervention's effect while keeping the intervention brief enough to be practical.

**A.6 Significance.** The numbers of VHA patients with AUDs diagnosed in the medical record are high and increasing (from 267,982 to 331,635 in a 3-year span).<sup>48</sup> The population of VHA patients treated for substance use and other mental health diagnoses increased by 38% in a 4-year span.<sup>49</sup> Among Veterans who received VHA services for at least one of five substance use and other mental health diagnoses (N=836,699), the majority of their health services use and costs was not attributable to services associated with these diagnoses, but rather to their non-substance use and non-mental health conditions, e.g., diabetes, cardiovascular conditions.<sup>49</sup> Of the study population, 50% had at least one serious physical health co-morbidity (21% had  $\geq 2$ ), and 20% were hospitalized during the study period of one year.<sup>49</sup> Thus, the co-occurrence of AUDs and medical-surgical conditions is associated with poor patient outcomes and substantial costs to VHA, underscoring the need for coordinated, patient-centered care across providers and conditions. A medical-

surgical inpatient episode presents a unique opportunity to address co-occurring AUDs, but prior research has not found support for existing approaches (BIs). Drawing on the large, interrelated MI, Decision Aid, and TM literatures, the proposed study will test a 3-pronged strategy among medical-surgical inpatients with AUDs on alcohol, medical, and treatment utilization outcomes over one year.

This proposal advances the VHA Blueprint for Excellence's Theme of healthcare innovation for Veterans and the country by using Strategy Six: "Advance health care that is personalized, proactive, and patient-driven, and engages and inspires Veterans to their highest possible level of health and well-being." This theme suggests the need for greater coordination of VHA services, while embracing the balance between patient self-determination and a system that seeks to provide care in the manner that the Veteran desires, based on his or her health conditions, motivation, values, and goals. Strategy Six objectives include VHA partnering with each Veteran to create a personalized, proactive plan to optimize health and well-being while providing state-of-the-art disease or disorder management. We propose an innovative approach to meeting this objective. Specifically, MI respects and works with patients' ambivalence about changing drinking, the Decision Aid informs patients about the evidence behind different help sources so that they can choose the help source they prefer based on their needs, and TM continues to work with ambivalence as needed and provide support for patients' choices. This proposal also addresses HSR&D priorities in the cross-cutting area of mental and behavioral health, in that it requires cross-service collaboration among medicine, surgery, and mental health-addiction services to enhance the continuum of care.

In this regard, evidence is growing that AUDs negatively impact readmission, length of stay, and postoperative outcomes among medical-surgical inpatients.<sup>49,50</sup> The Joint Commission's recommendation of screening for unhealthy alcohol use in all hospitalized patients is grounded in the recognition that AUDs are a major determinant of hospitalized patients' health. Better outcomes and cost savings are associated with intervening with AUDs among medical-surgical inpatients. AUD treatments reduce long-term comorbidities such as liver failure and lung cancer.<sup>51</sup> More generally, treatment of AUDs is associated with a decrease in total health care utilization and thus produces marked economic benefits for the treatment options of psychotherapy and pharmacotherapy.<sup>52</sup> These findings highlight the need for studies focused on identifying and facilitating AUD treatment entry among medical-surgical inpatients, thereby improving continuity of care and successful transitions to needed health care components.<sup>53,54</sup>

As recently presented by Dr. Bradley (Consultant) and Dr. Kivlahan (operations partner in VA Mental Health Services, now WOC, due to VA retirement in 2016 [Dr. Drexler, in Dr. Kivlahan's former VA position, also supports this project - see letter]),<sup>4</sup> patient-centered care incorporating informed decisions about drinking options and help initiation is essential for the delivery of effective AUD help. Making informed decisions involves a dialog between patients and decision coaches to assist patients to better understand their conditions and the need to make help decisions; provide information about benefits and adverse effects of help options; and support patients while they clarify their values and preferences and make and implement decisions. Implementing informed decisions for AUD in medical settings involves assessing AUD severity, medical and mental health comorbidities, previous help for drinking, reasons patients want to change or not change drinking, and help they want to do so. Using MI, discussions should cover ambivalence about change, goals (abstain, decrease drinking, stay the same), and help preferences (medications, behavioral treatments, 12-step groups, combinations) and settings (e.g., residential; individual or group outpatient). However, current approaches to managing AUDs stand in stark contrast to these concepts.<sup>4</sup> Although patient-centered care with informed decisions is not a new concept, it is not currently the routine approach to management of AUD in medical-surgical settings. Rather, at best, referral to specialty addiction care may be offered (or even made without the patient's knowledge), with no or little discussion of the patient's preferences related to care. Lack of discussion of patient preferences regarding type of help holds even when inpatient providers follow the Joint Commission's Inpatient ORYX Program, which asks simply if the patient agrees to further treatment (yes or no). Rates of treatment initiation following usual referrals are very low, highlighting the need for more patient-centered decision making.<sup>4</sup> A new meta-analysis and commentary by the PIs and colleagues found no evidence that BIs in medical settings have any efficacy for increasing receipt of alcohol-related services.<sup>55,56</sup>

The proposed project is highly innovative because it is the first to develop and test a strategy that is designed to increase Veterans' AUD help utilization that (1) is intensive enough to produce change yet feasible to use in busy clinical settings with already too much demand for too few staff; and (2) draws on approaches that are evidence-based but have never been used together in an integrated approach. The strategy should improve patients' understanding of the array of available evidence-supported AUD help options rather than presenting treatment as one undifferentiated choice. To facilitate discussions, the proposed project integrates MI to increase the likelihood that participants will be open to pursuing at least one type of AUD help. The

decision making literature highlights the helpfulness of conveying, with a decision aid, that there is more than one reasonable option for a treatment decision when no one option has a clear advantage, and that different people choose different options for different reasons. Finally, and also innovative, the proposed study will involve follow-up calls to help solidify motivation, and continue conversations about the decision of if, how, and where to seek AUD care. Although quite novel, this approach is consistent with the MI approach to AUD treatment presented by Bradley and Kivlahan (and Elwyn et al.<sup>27</sup>), which outlines a strategy for engaging AUD patients in decisions to improve treatment initiation and engagement and AUD outcomes.<sup>4</sup> It concurs with the VA/DoD guide on engaging patients in shared decision making, using MI and decision tools as key elements.<sup>57</sup>

In summary, there is a pressing need to address AUDs during medical-surgical hospital stays, but prior work has not found support for existing strategies during this critical time period. We propose to help medical-surgical inpatients with AUDs understand the benefits of reducing or abstaining from drinking, and of different types of AUD help, and to initiate and engage with the type of care decided upon. The 2010 Affordable Care Act included provisions to foster adoption of decision aids and governmental support for their expansion.<sup>58</sup> As required by the VHA Blueprint for Excellence that every research proposal clearly states how it will benefit Veterans and society, we anticipate that **DO-MoST will increase AUD-positive medical-surgical inpatients' utilization of evidence-based AUD help, improve AUD and medical outcomes, decrease use of acute care services, and thereby decrease societal harms and costs due to untreated AUDs.**

**A.7 Preliminary Studies.** The research team has a longstanding history of high-impact research on VHA addictions treatment and mutual-help use and on Veterans' help-related decision-making. Most relevant to the current proposal, the PIs completed a randomized trial (HSR&D IAC 09-055) of a MI intervention (in-person session, followed by weekly phone calls for 3 months) versus UC with psychiatry inpatients diagnosed with dual mental health and substance use disorders, to increase post-discharge use of specialty addiction treatment to improve outcomes. Of patients in the MI condition, 93% participated in the TM component of the intervention. Preliminary findings are that, at 1-year follow-up, compared to patients in UC (controlling for baseline drinking), patients in the MI condition reported significantly fewer drinking days in the past 90 days, and a lower percentage of days on which they drank. In addition, the number of consecutive days of abstinence was higher, and the number of consecutive drinking days was lower, for the MI group. These results suggest that telephone-based MI is a feasible, practical method of achieving clinically-meaningful improvements in alcohol-related outcomes among VHA dually diagnosed psychiatry inpatients. The 1-year follow-up rate exceeded 80%, consistent with our other projects (e.g., HSR&D IAC 09-047, Dr. Ilgen, PI).

In another IIR project (HSR&D CRE 12-010), the PIs conducted a Hybrid Type 1 study to facilitate the use of addiction treatment and improve outcomes among detoxification psychiatry inpatients. Detox provides medically-supervised withdrawal from a substance of dependence so that the severity of withdrawal symptoms and serious medical complications, which may be fatal, are reduced. The project compared MI techniques used during TM to UC. The proposed project differs from our previous projects because inpatients in medical-surgical settings (compared to dually diagnosed and detox psychiatry inpatients) require more extensive efforts to facilitate drinking behavior change, and their use of post-discharge addiction treatment services. Medical-surgical inpatients may not be aware that they have AUD, in contrast to dually diagnosed and detox inpatients who are hospitalized because of their substance use and mental health disorders. This project also differs from our previous projects because it reflects more recent scientific advancements recognizing the benefits of not only MI, but patient-determined decisions about drinking and help options, and of extended support and monitoring of decisions over time, in terms of improved outcomes.

## **B. Research Design and Methods**

**B.1 Overview.** A goal of this study is to make available a validated decision aid to enable providers to assist medical-surgical inpatients with AUD to make decisions about AUD help (Aim 1). Another goal is to determine whether adding DO-MoST (which incorporates MI, use of this decision aid, and TM) to usual inpatient medical-surgical care for Veteran inpatients with AUD, increases participation in AUD help (Aim 2, Hypothesis 1), improves alcohol use and medical outcomes (Aim 2, Hypothesis 2), and reduces subsequent acute care utilization (Aim 2, Hypothesis 3). Patients will be followed at 3 months (end of intervention for those in DO-MoST), and 6 and 12 months post-discharge. The project will also conduct a qualitative process evaluation to inform the future implementation of DO-MoST beyond the two sites in this project (Aim 3).

**B.2 Aim 1: Adapt an AUD Decision Aid.** We will adapt a Decision Aid currently being used with AUD patients in primary care settings so that it is applicable for Veterans with AUDs in medical-surgical inpatient settings. The existing Decision Aid meets International Patient Decision Aid Standards,<sup>59</sup> i.e., provides information about options and probable effects of taking each option (including course of disorder if no action is taken); presents the latest scientific evidence and options in a balanced way; uses plain language; supports the patient to clarify

and express values related to the decision; uses patients' personal histories to communicate options and model values clarification; provides guidance in patients' deliberations and communication of concerns or decisions; enables disclosure of conflicts of interest. Decision aids are tools to help health care consumers understand and clarify their choices and preferences in regard to a discrete decision. They list possible interventions, outcomes that might occur, and the likelihood of these outcomes.<sup>27,29</sup> Decision aids are offered in a variety of forms; this one is on paper. Decision aids improve patients' knowledge of treatment options, realistic expectations of treatment outcomes, comfort with choices, and agreement between values and choices, and decrease patients' decisional uncertainty.<sup>60,61</sup>

Using recommended methods (e.g., updated systematic review of the most recent literature on the efficacy and risks of evidence-based addiction treatments) and sample sizes,<sup>62-64</sup> with the prototype, at each site we will conduct alpha testing (face-to-face semi-structured interviews) with 5 medical-surgical inpatients with AUDs, and 4 providers (physicians, nurses, and social workers), in the same units in which the RCT will be conducted. We will also observe (5 per site) inpatient nurses and social workers as they administer alcohol screening and brief intervention (ORYX procedures required by the Joint Commission). Provider recruitment will follow procedures used successfully in our other projects interviewing treatment providers (e.g., QUERI RRP 12-525, which recruited 100% [N=30] of the target sample size). (Recruitment of non-providers is in Section B.3.4.) At each site, the PIs will contact by email each inpatient unit staff member to be interviewed to briefly explain the purpose of the project and invite the individual to participate. Emails will be followed with a phone call to answer any questions the staff member may have and schedule an interview time. If emails fail at contact, we will make phone calls or visit the inpatient unit in person. Staff members will provide informed consent prior to interview. Providers (prohibited by VA rules from receiving remuneration) will be interviewed in person while on or off duty, as they prefer.

Alpha testing will determine the ease and difficulty of understanding the Decision Aid (whether it needs to be even less complex) and the extent to which it is complete and applicable to the specific target population. Using cognitive "think-alouds," interviewees will be asked for their thoughts about the Decision Aid while reviewing the contents, e.g., parts that are hard to understand, extent to which patients would be sufficiently informed and supported, places needing more information. Think-alouds will include reactions about reading levels, use of technical terms and acronyms, and layout. Based on feedback during alpha testing, the study team will adapt the Decision Aid. The Decision Aid will then be piloted with 5 patients (not in the alpha test) and 4 providers (in and not in the alpha test) at each site for finalizing it before use in the RCT.

### B.3 Aim 2: RCT of Drinking Options: Motivate, Shared Decisions, Telemonitor (DO-MoST) vs Usual Care (UC)

B.3.1 Power analysis. Based on previous research using MI or SDM approaches with inpatients to improve addiction treatment rates and outcomes, we expect to observe at least a medium effect size (.50) between the UC and DO-MoST groups in AUD help initiation and duration and alcohol use outcomes, e.g., percent of heavy drinking days, an FDA-recommended outcome, on which differences should be clinically meaningful.<sup>65-67</sup> (For example, among treated AUD patients, the mean percent of heavy drinking days in the past 90 days decreased from 66% at baseline to 17% at 4-month follow-up.<sup>68</sup>) We expect a smaller effect size in endpoint rehospitalization rates.<sup>26</sup> We are planning to recruit a total sample of 156 patients (78 in each condition), which accounts for expected attrition. The sample will be stratified by site such that 78 patients will be recruited from VA Palo Alto, and 78 from VA Ann Arbor; at each site, 39 patients will enter each of the 2 conditions (UC or DO-MoST). These two sites were selected for this project because they have a high volume of medical-surgical inpatients with AUD (B.3.3) and differ geographically, and the two HSR&D COINs and PIs have a strong record of productive collaboration. In our recent joint project, rates of recruitment and follow-up were similar between sites.

B.3.2. Study population. Demographic characteristics of Veterans at the two sites are quite similar to those of Veteran medical-surgical inpatients nationwide.<sup>15,16,71</sup> We expect that about 94% of participants will be male, and their mean age will be 60 years old (24% <50, 27% 50-64, 41% 65-79, 7% >79 years old). At Palo Alto, about 76% will be White, 9% Black, and 16% Hispanic; at Ann Arbor, about 86% will be white, 11% Black, and 2% Hispanic. Nationally, Veterans are mainly White (82%), with 12% Black, and 7% Hispanic.

B.3.3. Eligibility criteria for patients' study participation are (1) in a current episode of inpatient medical-surgical care, (2) meet DSM 5 criteria for an AUD (moderate or severe), (3) no specialty addiction treatment or weekly mutual-help group attendance within 60 days prior to the inpatient episode,<sup>22,72</sup> (4) no restricted access due to infection control requirements (e.g., TB, MRSA, C. diff), (5) no significant cognitive impairment, (6) ongoing access to a cell or landline telephone, (7) at least one contact who will continue to know the patient's contact information, and (8) not having participated in an interview for Aim 1. In FY14, 469 unique patients at VA Palo Alto, and 453 unique patients at VA Ann Arbor, had an inpatient medical-surgical stay, an AUD diagnosis, and

no specialty addiction treatment within the 60 day period preceding the stay.<sup>1</sup> In our HSR&D projects on Veterans in inpatient psychiatry, 14% of potential participants were ineligible due to infection control restrictions, cognitive impairment, lack of ongoing phone access, and/or lack of at least one contact. Excluding up to 15% of inpatients with AUD due to ineligibility leaves 399 and 385 eligible patients per year at VA Palo Alto and VA Ann Arbor, respectively. Of patients who meet eligibility criteria, we expect (based on our current project, achieving a 78% consent rate) that at least 75% will agree to participate - a minimum of 299 patients per year at VA Palo Alto, and 289 patients per year at VA Ann Arbor. Therefore, our plan to recruit the sample of participants over 1.5 years is clearly feasible. Because we are successfully recruiting participants at a similar rate in our ongoing HSR&D project on inpatient detox, we are confident that we will achieve recruitment goals for this study. Although we could enroll patients at a faster rate, we plan to recruit at the proposed pace because a faster rate would overload Decision Coaches providing the intervention, and research assistants conducting intake and follow-up assessments.

**B.3.4. Procedure.** During study recruitment, all medical-surgical inpatients in VA Palo Alto or Ann Arbor will receive UC, that is, receive ORYX alcohol procedures in which the admitting nurse administers the AUDIT-C. Men scoring  $\geq 4$ , and women scoring  $\geq 3$ , on the AUDIT-C (i.e., positive screen), with no restricted access due to infection control requirements, will be asked if they are willing to be contacted about the project. Patients who agree will be approached in person by project staff. To ensure recruitment of female participants, we will emphasize that every eligible female patient who has agreed should be approached about the study. Nursing staff will provide study personnel with a list of potential participants each weekday. We are confident that they will refer patients to the study because we have successfully used such procedures involving screening and referral in other HSR&D studies (both Palo Alto and Ann Arbor), and inpatient medical-surgical directors at Palo Alto and Ann Arbor concur with this planned procedure. If the number of patients referred to the study exceeds recruitment goals, we will randomly select as many patients as needed (first, by days for recruitment, and then by patients if there are still too many). The research assistant will confirm eligibility based on DSM 5 criteria (2-3 symptoms out of 11 indicating mild AUD; 4-5 indicating moderate AUD;  $\geq 6$  indicating severe AUD), determine eligibility on the remaining criteria (cognitive function, no past-60 days AUD treatment or weekly mutual-help, phone access, available contact, non-participation in Aim 1), explain the study to potential participants, and obtain informed consent. Cognitive impairment will be assessed with the Montreal Cognitive Assessment's section on Orientation.<sup>73</sup> Patients not able to correctly answer Orientation (date, location) items will be deemed ineligible (too cognitively impaired to understand study procedures and interviews). Consented patients will be randomly assigned to UC or DO-MoST using random numbers generated by randomizer.org. The mean VHA length of hospitalization for surgery is 9 days, and of medical stays 4 days,<sup>74,75</sup> these are slightly longer than inpatient psychiatry and detox stays, for which we have successfully used similar procedures as planned for this study.

Number and length of the project's in-person and phone sessions will not be matched between conditions. An important component of DO-MoST is its supportive nature, apart from specific content. It would be quite difficult to match time and attention DO-MoST and UC groups receive without also equating support. **UC.** All patients, regardless of condition, will receive usual inpatient care at the Palo Alto or Ann Arbor VA. At both sites, implementation of ORYX measures requires that, under usual care, when a patient screens positive on the AUDIT-C administered at intake, a provider (social worker, nurse) provides BI, i.e., tells the patient that problems are associated with alcohol use, and about recommended drinking limits; notes the patient as ready to change drinking or not, and as agreeing to treatment or not. If the patient agrees to treatment, specialty addiction services are notified. Both sites have addiction outpatient and residential specialty care offering behavioral therapies (the 4 targeted in this study), pharmacotherapy (the 3 targeted in this study), and 12-step meetings, and Patient Aligned Care Teams within primary care.

**DO-MoST.** Patients assigned to the DO-MoST condition will receive usual care plus the DO-MoST intervention. They will attend one 50-minute individual session during their inpatient stay with a Decision Coach (a trained clinical provider, e.g., MSW). Patients in DO-MoST will also attend 6 biweekly 15-minute telephone sessions from the same Decision Coach. In our current HSR&D project with detox inpatients, 100% of patients completing a baseline interview also participated in the inpatient session with the TeleCoach.

At the initial session, the Decision Coach and patient will engage in MI to discuss the patient's medical condition and need to make decisions about drinking goals, and their benefits and adverse effects, i.e., abstinence vs. moderation vs. no change. MI components include empathy when giving personalized feedback (Engage); conveying the patient's responsibility for change (Focus); and support of the patient's self-efficacy to make changes (Evoke, Plan). MI includes reviewing patients' values (e.g., good health and relationships) and substance use patterns and their consequences. The discrepancy between patients' substance use and ability



to meet values, and the use of a “change plan,” such as engaging in addiction treatment, mutual-help, and other health care appointments, are discussed. If the patient’s preference is to reduce or abstain from drinking and the patient is willing to consider obtaining help, the Decision Aid will be employed to present evidence-based help options (3 medications; 4 behavioral therapies; mutual-help) and their benefits, adverse effects, and settings (primary care, specialty care [residential, outpatient], community, combination).<sup>4,31</sup> The Decision Aid will not consider other potential help sources such as enlisting the aid of family, friends, or religious counselors, or using online resources, to change drinking, because evidence is lacking for these and measures of their quality and amount are not standardized. At the end of this session, patients will complete a brief measure of their drinking and help preferences.<sup>4</sup> If the patient is ready, a printed list that includes the location and contact number for each potential selected source of help will be used, to make concrete the next step in obtaining AUD help.

Telephone sessions (in Appendix) will be adapted from our current manualized protocol using MI with detox inpatients after an in-person session; the in-person session helps overcome the potential barrier of being less likely to engage in phone calls with a provider patients have never met.<sup>76</sup> Patients in DO-MoST will be expected to complete one 15-minute phone call every 2 weeks for 12 weeks by answering calls at predetermined times. When patients fail to answer a call, the Decision Coach will make at least 2 more attempts to contact the patient for that scheduled contact, and when successful, the initial failure will be discussed. During each telephone session, patients will complete the Progress Assessment Worksheet<sup>77</sup> which includes drinking and help preferences, and questions about recent substance use, treatment and mutual-help. TM when “no” to help. Patients indicating during the inpatient session that they do not want to change drinking or initiate help will receive MI during the biweekly telephone calls. We expect that patients who choose not to initiate help will participate in TM because experience in our own projects agrees with the research literature that even medical patients who report they are doing well are more satisfied with their care when providers continue to monitor and support them.<sup>78</sup> Decision Coaches will be trained to use phone calls as part of DO-MoST to positively reinforce even small steps toward recovery and to react non-judgmentally to set-backs. Guidelines for phone sessions state that the patient’s status should be considered in how to proceed. The Decision Coach will explain the overall approach (not trying to change the patient), elicit self-motivational statements, and use reflection. Elicited will be the perceived possible benefits of help and likely negative consequences of not obtaining help for alcohol use. Decision Coaches will seek to obtain whatever commitment to obtaining help that is possible. They will focus on patients’ views of negative aspects of using alcohol by eliciting patients’ personal goals, helping the patient assess how drinking hinders progress toward those goals, and giving personalized feedback on the hazards and risks of drinking. To foster commitment to change drinking behaviors, Decision Coaches will use the techniques of developing the discrepancy between current behaviors and values. As sessions progress, Decision Coaches will help patients reassess their drinking-related behaviors and the effectiveness of aspects of their plans. Later telephone sessions (guided by patients’ progress) will focus on continuing to build patients’ successes at achieving values, supported and assisted by the Decision Coach. Importantly, in our prior work using TM following an inpatient psychiatry stay for those with dual diagnoses, we were successful in retaining individuals who were abstinent and those who relapsed. Some patients who initially do not prefer to initiate help may subsequently choose help initiation (Figure 1), in which case the protocol immediately below will be used.

TM when “yes” to help. Among patients indicating, during the inpatient session, willingness to initiate help, the extension of DO-MoST over time via the biweekly phone calls is necessary because patients coping with a medical-surgical hospitalization and with chronic conditions such as AUD need more support in the treatment decisionmaking process to move to decision implementation.<sup>79</sup> Phone calls will be used to make sure patients understand the help options available, and the consequences in terms of benefits and risks of each. They will ensure that patients have enough time to consider and digest the available options in the post-discharge period, and that patients are clear on the specific next step needed to pursue the selected help option. Further, TM will provide support when help is obtained, and problem-solving on barriers to help-initiation, or dislike of help obtained. For example, Coaches will help patients work through the potential situation that an AUD treatment provider suggests a different treatment option than the one the patient has selected. TM will support patients in moving from help-initiation to help-engagement.

**B.3.5. Decision Coaches’ training and supervision.** Having two Decision Coaches, one at each site, increases confidence in the generalizability of findings and manages logistical issues (filling in for each other on the phone when taking leave). Because Coaches will not have contact with patients in UC, contamination between the DO-MoST and UC conditions should not occur. Nevertheless, avoiding contamination (which would occur by giving intervention-related in-person and phone sessions to patients in the UC condition) will be stressed in

training and ongoing supervision. A 2-day training in Palo Alto for the Decision Coaches on the DO-MoST protocol will be led mainly by Dr. Blonigen, assisted by other study team members; Dr. Blonigen will also provide ongoing supervision of the Coaches. Training will begin with the rationale for the present study, a review of the unique needs and challenges of medical-surgical inpatients with AUD, and a summary of the literature on the impact of MI, Decision Aids, and TM. This will be followed by more specific training on the DO-MoST intervention protocol. Exercises for using the Decision Aid will include observation, discussion, and roleplays. The specifics of the phone sessions will be reviewed: structure, how to review status with the progress assessment method, use of MI-adherent behaviors to boost problem recognition and motivation to make decisions regarding help participation (for patients initially choosing to maintain drinking and not initiating help), and help-support and problem-solving (for patients choosing to reduce or abstain from drinking and initiate help). Coaches will roleplay in-person and phone sessions that will be audiotaped, coded for fidelity, and reviewed with supervision and feedback. After training, we will ensure the Coaches' readiness to deliver DO-MoST with a start-up practice phase during which Coaches will deliver DO-MoST to patients enrolled and assigned to the DO-MoST condition, but these patients will be considered training cases and not included in analyses. When Dr. Blonigen agrees that Coaches are consistently following the DO-MoST protocol, they will be certified to begin conducting sessions with non-practice participants.

**B.3.6 Baseline measures.** Research assistants will collect baseline self-report data from patients in person during their inpatient stay when they are stable. In our projects with psychiatry and detox inpatients, we collected baseline data from 98% of consented patients during the inpatient stay, even though stays were often quite brief (2-3 days). Areas assessed will include demographics (gender, age, race, ethnicity, education, employment, income, marital status, living situation); drinking and help preferences; substance use and medical status; related functioning; and VA and non-VA treatment history. The intake assessment will take about 1 hour (as shown by pretesting). If patients tire, it will be broken down into segments. Information on recent VA health services utilization will also be collected via patient records. Reviews of studies with medical patients that targeted alcohol and other drug use have not found an assessment reactivity effect.<sup>80</sup>

**Preferences.** We will measure patients' preferences regarding drinking and help using the same measure used in the in-person session with the Decision Coach.

**Substance use and medical outcomes.** We will use the Timeline Follow-Back (TLFB)<sup>81,82</sup> to assess substance use during the 30 and 90 days preceding baseline. The TLFB is a widely used, standardized, calendar-based retrospective self-report assessment to quantify daily substance use. For alcohol, we will examine the primary outcomes of abstinence, percent of drinking days, and percent of heavy drinking days, i.e.,  $\geq 4$  standard drinks per day for women,  $\geq 5$  for men. The TLFB also measures the most consecutive days of drinking, and most consecutive days abstinent. For the secondary outcome of drug use, we will examine percent using days, most consecutive days of using, and most consecutive days abstinent. The TLFB yields high temporal stability, validity, and agreement between self-reports and biological tests, collateral reports, and official records (from hospitalizations, jail stays). To assess medical status, we will use the Veterans SF-12, a 12-item self-report questionnaire that has been widely used and documented as a reliable and valid measure of the functional effects of illness in VHA patients.<sup>83</sup> SF-12 responses are aggregated into a physical component summary (PCS) score, constituting a primary outcome that reflects overall physical health status. Lower summary scores indicate worse health, and Veterans' SF-12 scores are related predictably to differences in morbidity, healthcare needs, and healthcare expenditures.<sup>84-86</sup>

**Help utilization.** We will use the TLFB to assess patients' use of VA and non-VA help for alcohol and drug use (type and amount of pharmacotherapies, behavioral treatments, mutual-help groups), including setting (inpatient, residential, outpatient, primary care, e.g., BIs). Primary outcomes for alcohol are any help use (yes/no for initiation) and duration of use (engagement). The primary outcome for engagement will be duration (not completion) of treatment because the duration and continuity of care are more closely related to outcomes than is treatment completion;<sup>87</sup> and our operations partners stated that in light of adaptive treatments, treatment completion is not cut-and-dried among AUD patients, such that duration is more reliable and meaningful. In addition, recommendations (e.g., from NIH) are that help be obtained for at least 1-2 years when beginning recovery from AUD;<sup>88</sup> such sustained help is needed to "retrain brains" affected by chronic alcohol use. We will also use the Addiction Severity Index (ASI)<sup>89</sup> to assess the participant's VA and non-VA history of lifetime treatment use including addiction, mental health, and medical-surgical care (outpatient, inpatient, residential, emergency). Data on non-VA health services use will be collected at baseline and follow-ups to help determine whether the two condition arms are balanced and ensure that any observed changes in VHA services use are not due simply to changes in non-VA care.

Related functioning. We will use selected portions of the ASI to fill in information missing from the TLFB and Veterans SF-12. The ASI, used to monitor VHA addiction patients' outcomes systemwide and in our projects, is a structured, clinical research interview that assesses 4 problem areas in addition to substance use and medical status: psychiatric, family/social, legal, and employment. In each area, a composite score is produced from items that are standardized and summed to provide an internally consistent evaluation of patient status in the past 30 days.<sup>89</sup> Scores range from 0 to 1, with higher scores indicating poorer outcomes.

Motivation, commitment, and self-efficacy. Motivation to change substance use will be assessed with the Readiness Ruler.<sup>90</sup> Used extensively across treatment settings, this method asks patients about motivation, for alcohol and drugs separately, on a scale of 1 (less – not ready to change) to 10 (more – trying to change). Patients will also complete the Commitment to Abstinence scale.<sup>91</sup> It has five summed items (e.g., I should never use any alcohol and drugs again) on which patients note extent of agreement. The scale has good validity, sensitivity to treatment-related change, and internal consistency across treatment settings and substance type.<sup>91</sup> Self-efficacy will be assessed with the Brief Situational Confidence Questionnaire.<sup>92</sup> Eight items ask patients to rate their confidence in resisting drinking and using drugs in different situations (e.g., physical discomfort), and then responses are averaged so that higher scores indicate more self-efficacy.

Decisional conflict. Decisional conflict, experienced by a patient who is uncertain about the best course of action, is a key outcome of Decision Aid use because high levels are associated with distress that interferes with effective decision making.<sup>27,29</sup> We will use the self-report Decisional Conflict Scale, which is frequently used to assess Veterans' decision certainty and comfort.<sup>93,94</sup> The scale's 16 items yield five subscales (Informed; Values Clarity; Support; Uncertainty; and Effective Decision) and a total score.

B.3.7 During-treatment assessments. The start-up period in which Decision Coaches are trained will be important to establishing the fidelity with which DO-MoST is delivered. To assess the integrity of the DO-MoST condition throughout the study, sessions will be evaluated against a protocol checklist (adapted from Drs. Bradley and Hawley's Decision Aid studies, and from the PIs' previous and ongoing MI-TM studies with psychiatry and detox inpatients). All phone sessions will be audiotaped (with appropriate consent). Phone sessions will be evaluated by Dr. Blonigen (assisted by the PIs) under the following schedule: (1) the first 15 phone calls for each Decision Coach will be assessed for protocol fidelity, and the Coach will be provided corrective feedback, and (2) eight calls will be reviewed at random each month to ensure ongoing fidelity of the intervention. No problems with adherence or responding appropriately to feedback were noted previously.

B.3.8 Follow-up assessments. Patients' follow-up data will come from administrative data in the VA Corporate Data Warehouse (CDW), and patient self-report. CDW data will cover behavioral health provided within primary care and addiction specialty care encounters, i.e., entry into addiction treatment, and types, timings, and durations of treatments. Self-report data will include drinking and help preferences; use of alcohol (and other drugs); medical status; help participation; other functioning; and potential explanatory mechanisms linking help to outcomes, i.e., motivation, commitment, and self-efficacy to change alcohol-related behaviors; decisional conflict about help.

Research assistants, blinded to patients' condition assignment, will collect self-report data by telephone at 3 months, which will be upon completion of the intervention for the group in the DO-MoST condition, and then 6 and 12 months post-baseline. We will use an intent-to-treat design and so will follow patients who do not complete the intervention. Six months is a necessary follow-up point because most (60%-80%) patients treated for AUDs who relapse do so within this interval. Twelve months is a necessary follow-up point because the 6 months preceding that time point continue to be of high risk for relapse. Follow-up assessments will be conducted by telephone because patients may not reside in close geographical proximity to the Palo Alto or Ann Arbor VA. As noted (A.7), we have successfully used telephone interviews to collect follow-up data in HSR&D studies with inpatients. Follow-up interviews will take approximately one hour each. Patients will have the option of completing the interview in shorter sessions, with breaks, due to scheduling needs or fatigue.

We will measure patients' drinking and help preferences using the same measure with the Decision Coach at baseline. We will use the AUDIT-C, DSM 5 for alcohol diagnoses, TLFB, and SF-12 to measure substance use and medical status at follow-ups, supplemented by portions of the ASI. The TLFB (covering the period since the prior interview at each follow-up) will assess the same primary alcohol outcomes (abstinence, percent of drinking days, of heavy drinking days) and other substance use indices assessed at baseline. The ASI will provide recent (past 30 days) alcohol and drug use composite scores. The TLFB and ASI are valid and reliable when given by telephone.<sup>86,92</sup> We will be able to compute dichotomous scores regarding abstinence from alcohol, drugs, and both alcohol and drugs over the assessed periods. The SF-12 will yield the primary outcome reflecting overall physical health status.

The TLFB will also be used to measure self-reported VA and non-VA alcohol-related, mental health, and medical help (treatment types, amounts, and settings) since the previous interview. Primary outcomes will be any use of alcohol help, and duration (weeks) of help. The ASI's selected portions on functioning will produce psychiatric, family/social, legal, and employment composite scores, and assess housing status. We will use measures used at baseline to assess motivation to change alcohol use, commitment to abstinence, self-efficacy to resist drinking, and Decisional Conflict with regard to drinking help options at follow-ups.

B.3.9 Procedures to Locate and Follow Patients. To ensure high follow-up rates, we will adhere to well-established procedures for locating and following substance use disorder, psychiatry, and medical patients in longitudinal studies. We have extensive experience in retaining research participants using proactive retention strategies, tracking protocols, and interviewer training procedures. Our Centers have conducted long-term studies with extremely high follow-up rates, e.g., 80% among individuals with AUDs followed for 16 years, 80% among depressed patients and controls followed for 23 years; 92% for addiction patients at 1 year, and 84% for dual diagnosis patients at 2 years. Our retention strategies include (1) research assistant interviewers are comfortable with the population under study and trained to establish rapport, (2) maintain toll-free telephone numbers for participants to report contact information changes (especially useful for patients who may lose their ongoing access to a telephone during the study), (3) obtain and verify in-depth locator and tracking information at intake, and update records at each interview and between interviews, (4) maintain consistent contact between interviews (e.g., thank you cards to enhance rapport and verify addresses), (5) keep detailed records of every contact and contact attempt, and (6) use the internet for tracking (e.g., Department of Corrections websites). We will use these procedures to target follow-up rates of at least 70%.

B.3.10 Measuring Use of VHA Health Care Services. We will collect data on participants' use of VHA health care, including services from behavioral health providers in primary care, and addiction, mental health, and medical-surgical services.<sup>95</sup> These data will be used to address the hypothesis that patients in DO-MoST, compared to patients in UC, will be more likely to enter alcohol treatment and attend treatment for a longer duration, and have fewer and delayed (i.e., greater number of days until) acute care episodes (Aim 2, Hypotheses 1 and 3). The data source for VHA health care utilization will be the CDW for VHA-provided inpatient, residential, and outpatient care, pharmacy services, and primary care behavioral health. We will also search the Fee Basis files for all records for study participants.

To measure the utilization of VHA care, we will obtain all records for study participants for all health care encounters that occur in the one-year period prior to, and ending one year after, study enrollment (i.e., one year post-index hospitalization). Variables extracted from records of inpatient or residential care will include patient ID (SCRSSN), station, treating specialty (bedsection), date of service, diagnosis and procedure codes, and length of stay. Variables extracted from records of outpatient care will include patient ID, station, clinic stop code, date of service, diagnosis and procedure codes, and numbers of visits. Variables extracted from records of primary care encounters will include patient ID, station, date of service, and procedure codes indicating behavioral health care provision. We will classify VHA care as pertaining to addiction, psychiatry, or medical-surgical conditions based on stop code or treating specialty code. Fee Basis care will also be classified by setting and purpose of visit.

To assign hospital stays with multiple bedsections to a single category, we will classify inpatient stays to addiction if there is such a bedsection segment, to psychiatry if there is a psychiatry bedsection segment, and to medical-surgical otherwise. Outpatient care will be classified as addiction, psychiatry, or medical-surgical based on clinic stop codes. Emergency Department visits will be identified through clinic stop codes. Prescription drugs will be classified as AUD, medication-assisted treatment for opioid use disorder, psychiatry, or medical-surgical based on the VHA drug class.

B.3.11 Analysis Plan: Overview. In the RCT (Aim 2), primary hypotheses are that patients in DO-MoST, compared to those in UC, will be more likely to (1) enter addiction treatment or mutual-help (initiate), and attend it for a longer duration (engage); (2) have better alcohol use and medical outcomes; and (3) have fewer and delayed (greater number of days until) acute care episodes. To address these hypotheses, preliminary to regression modeling, we will check the distribution of the outcome and predictor variables, detect and adjust for missing data,<sup>96</sup> and examine the baseline equivalence of the DO-MoST and UC groups. We will then evaluate the effect of the DO-MoST intervention on primary (addiction help utilization, alcohol and medical outcomes, acute care utilization) as well as secondary related outcomes, using generalized mixed-effects regression models (GLMM) appropriate for the distribution of the outcome variable and error term, and examine mechanisms of effects (the reasons DO-MoST is effective, and for whom).

Compare DO-MoST and UC conditions. We will use GLMM regression analyses to compare the UC with the DO-MoST condition on help utilization (e.g., any, and duration of, alcohol help; type of help), alcohol outcomes

(e.g., abstinence, percent of heavy drinking days), medical status, and related outcomes, and acute care utilization (rehospitalization, emergency department visits) over the 1-year follow-up period. Advantages of GLMM regression are that it permits regression modeling of repeated-measures data; does not require that all participants be measured at all time points to be included in analyses; and applies to continuous, dichotomous (e.g., any addiction help, abstinence, hospitalization), and Poisson-distributed outcomes (e.g., number of outpatient visits or inpatient days).

In the regression model, we will take into account that the repeated measures over the four time points are clustered within each individual by treating time as a single repeated factor. As part of model building, we will examine error distributions to assess whether random effects meet the assumptions of normality and homoscedasticity, and adjust models as needed. Specifically, we will first specify the appropriate distribution of the outcome variable in the regression model (e.g., normal, binomial, Poisson) and choose the appropriate link and variance functions. The main factor of interest is condition (UC, DO-MoST). For each dependent variable, a linear trajectory for each patient will be estimated. The intercept is the estimate of the patient's score at intake. The slope is the estimate of the linear response trajectory, and the error represents how well the linear model fits the patient's data. For each outcome, three among-person parameters will be estimated: (a) the average baseline score for each group (UC, DO-MoST); (b) the average slopes over time for the UC and DO-MoST groups; and (c) the interaction effect of condition by site. We will employ full maximum likelihood estimation. In combination with random effects, we will examine further constraints on covariance structure (e.g., auto-regressive) and choose that which yields the best fit by standard goodness-of-fit measures (e.g., Akaike's Information Criterion). This method will yield estimates of the effects of the DO-MoST condition on addiction help, alcohol, medical, and related outcomes, and VHA or non-VHA acute care services utilization. Specifically, we will examine whether patients in DO-MoST have fewer and delayed acute care episodes (rehospitalization, emergency department visits) compared to patients in UC. We will use the GLMM regression model in analysis of number of episodes. Time until episodes will be regressed on condition (UC, DO-MoST), site (Ann Arbor, Palo Alto), and patient demographic characteristics using Cox regression models.

Because DO-MoST will be standardized and monitored for fidelity (with correction if there is drift), we do not expect variations in outcomes associated with the Decision Coach. However, to be safe, we will specify a model where random effects of patients will be nested within random effects of Coaches. If the fit of the model is similar to one without nesting within Coaches, we will not continue to control for it.<sup>97</sup>

**B.3.12 Examine mechanisms (reasons DO-MoST is effective).** Alcohol help initiation and engagement will be examined as mediators between condition and outcomes.<sup>98,99</sup> We will conduct a series of regression models (controlling for covariates, e.g., baseline value of the dependent variable) that correspond to a hypothesized causal sequence among (1) DO-MoST, (2) alcohol help utilization, and (3) better alcohol and medical outcomes. First, the dummy variable representing DO-MoST is the independent variable and the dependent variable is the outcome (e.g., abstinence, percent of heavy drinking days). In the second regression, DO-MoST is the independent variable and the dependent variable is the potential mediator (e.g., duration of alcohol outpatient help). In the third regression the potential mediator is the independent variable and the dependent variable is the outcome. If the coefficient for DO-MoST or potential mediator is significant in all cases, we will proceed. In the final regression, DO-MoST is entered simultaneously with the utilization variable as predictors of the outcome. If the coefficient for utilization is significant and the coefficient for DO-MoST on the outcome is reduced, then we will conclude that a mediating effect of utilization is supported, and evaluate whether the indirect effect of DO-MoST on the outcome via treatment is significant.<sup>100</sup>

We will also determine if increases in treatment utilization associated with DO-MoST are mediated by the mechanisms of reduced decisional conflict and increased motivation, commitment, and self-efficacy. We will conduct a series of regression models that correspond to a hypothesized causal sequence among (1) DO-MoST (vs. UC), (2) the potential mechanisms, and (3) use of alcohol treatment, and control for covariates. Analyses will use the same general linear model approach described in the previous paragraph. We will conduct regression analyses (covariates controlled) to examine associations of DO-MoST dose (number of phone sessions completed) with patients' outcomes at follow-ups, using methods (e.g., instrumental variables) to account for possible problems associated with endogeneity.<sup>101</sup> We will explore whether less intensive (e.g., 3-session) doses of DO-MoST are as effective as the full, 6-session dose.

Additional analyses will explore patients' baseline level of AUD (moderate or severe) as a moderator of condition-outcome associations; the needed interaction term (condition by diagnosis) will be added to the GLMM regressions. Results will indicate, for example, whether DO-MoST has a stronger association with patients' improved drinking when AUD symptoms are more severe. We will also examine patient age (e.g., <50, 50-64, >64 years old), race (e.g., white, not white), and homelessness as potential moderators; for

example, DO-MoST may be more effective when veteran patients are homeless.<sup>102</sup> Although we will attempt to enroll every eligible female patient into the study, we are still unlikely to have enough women to conduct gender-related analyses. This will require examining DO-MoST at additional numbers of sites in subsequent studies to yield larger numbers of women who are medical-surgical inpatients with AUD.

**B.4 Aim 3: Process Evaluation of DO-MoST.** We will conduct a process evaluation to document critical factors at the system-, provider-, and patient-levels that affect the likelihood that DO-MoST could be implemented and sustained in VA, and the extent to which it needs to be adapted to be most effective with specific Veteran groups, such as patients with co-occurring mental health disorders (PTSD), women, and OEF/OIF/OND Veterans. We will use the RE-AIM Planning Tool<sup>5</sup> to conduct semi-structured interviews with Key Informants, that is, providers of services to medical-surgical inpatients with AUDs, and patients with AUDs receiving medical-surgical inpatient care. The RE-AIM framework highlights information needed to evaluate an intervention's potential for implementation and widespread impact, including its *Reach* (how to reach the target population with DO-MoST: number, percent of target patients, and representativeness of patients who agree to DO-MoST), *Effectiveness* (how to know DO-MoST is effective: change in outcomes), *adoption* (organizational support: number, percent, and representativeness of target settings and providers who participate in implementation), *Implementation* (fidelity of DO-MoST's delivery; its time, costs), and *Maintenance* (sustainability). The RE-AIM Planning Tool asks questions of providers and patients within each framework domain regarding key issues that should be considered when planning implementation, for example: *Reach*: How to ensure that *all* medical-surgical inpatients with AUD accept DO-MoST; confidence that DO-MoST will attract all such inpatients despite mental health (PTSD), demographic (gender), and other factors. *Effectiveness*: Strengths of, and benefits anticipated from, DO-MoST; unintended negative consequences. *Adoption*: Greatest barriers to inpatient medical-surgical units adopting DO-MoST and systems for overcoming them; sources of potential staff resistance to DO-MOST; development of organizational support. *Implementation*: Ensure DO-MoST is delivered properly despite customization to facilities. *Maintenance*: Incorporate DO-MOST locally so that it is delivered over the long term, integrated into the regular practice of VA facilities. *Distribute ownership for implementing DO-MoST among inpatient medical-surgical, addiction, and other (primary care, social work, nursing) services.*

Interviews will help explain barriers to setting, provider, and patient participation in DO-MoST and how to address them; provider and patient perceptions about why DO-MoST is successful at achieving better outcomes; barriers to implementation of DO-MoST – site specific, and general -- and how to address them; and perceived value of, and how to sustain, DO-MoST in the absence of a funded project. They will also help plan if and how DO-MoST should be adjusted to appeal to and help subpopulations (female, OEF/OIF/OND).

The PIs will prepare a draft interview guide and finalize it with feedback from the project team (having had QUERI funding for similar evaluations) and pre-testing with 2 medical-surgical inpatient unit staff (physician, nurse). Recruitment and interview procedures for providers will be similar to those for Aim 1. Interviews will be conducted by the project's senior staff and research assistants who will be trained in carrying out such interviews (we have successfully conducted trainings before). We will interview 12 staff members at each of the 2 sites, including medical-surgical units' directors, other physicians, nurses, social workers, and administrators. Providers who participated in Aim 1 interviews will not be excluded from Aim 3 interviews because the Aims are related but do not overlap; the same staff members, such as unit directors, would provide crucial input for both Aims; and there will be a sizeable time gap between interviews. We will also interview addiction treatment providers within specialty and primary care teams at each site. Further, we will conduct interviews with 12 patients at each site; one-half will have received the intervention, and one-half will be in UC. Individuals cannot represent entire groups, but we will include Veterans from different groups based on mental health diagnosis, age, gender, and other factors. Interviews will be audiotaped when consent is given, conducted in person when possible and by phone otherwise, and last 30-60 minutes.

**B.4.1 Analysis Plan.** Using rapid analysis methodology,<sup>103</sup> the PIs will listen to the interview transcripts and take detailed notes using the structure of the interview guide questions. We will focus on the components of the RE-AIM model to optimize the potential for implementation and sustainable adoption of DO-MoST across VA facilities, by creating tables regarding DO-MoST that will then be reviewed by the Co-Investigators. Tables will summarize and categorize barriers and facilitators by the patient, provider, and system levels and include potential solutions and potential-to-leverage columns that contain evidence-based implementation tools to be considered for more widespread usage of DO-MoST. Such factors will be used to inform interpretation of project findings and optimize subsequent implementation plans. In conjunction with the tables, we will develop a small set of key themes in each RE-AIM component that signify triangulated findings. We will identify factors facilitating and maintaining units' use of DO-MoST to reach medical-surgical inpatients with AUD and help

