Study Title: Specialized Community Disease Management to Reduce Substance Use and Hospital Readmissions

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Treatment Research Institute—Institutional Review Board

SUMMARY OF HUMAN SUBJECTS RESEARCH PROTOCOL

Please address all applicable points to create a complete and succinct synopsis of the protocol. Use language, insofar as is possible, that can be understood by an external, non-scientist layperson, and provide meanings for all acronyms used. **Form must be typewritten.**

(Maintain subheadings in body of text.)

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1. Introduction and rationale for study

Hospitalized patients with substance use disorders (SUDs) face significant complications in their medical care. They are more likely to be discharged against medical advice, rehospitalized after discharge, and experience personal chaos and reduced family support. Rapid rehospitalization (RRH) is receiving increasing focus as a healthcare quality issue, and the Centers for Medicare and Medicaid Services (CMS) have instituted penalties on hospitals where there is a significant rate of RRH within 30 days. Currently, hospital penalties are adjudicated based on the RRH rates of three conditions: congestive heart failure, acute myocardial infarction, and pneumonia. Due in large part to these Medicaid penalties, hospital systems are moving quickly to implement hospital-based and community disease management strategies to help patients transition post-discharge. However, few hospitals provide specialized follow-up for discharged patients with SUDs. Inpatients with substance use disorders may not be served well by existing disease management programs intended to reduce rehospitalizations because the programs do not attend to their SUD and related psychosocial problems (isolation, unstable housing, mental illness, HIV infection, etc.).

The Institute for Population Health at Temple University Hospital (our partner in this project) has partially reduced the 30 day RRH rates for discharged patients who are diagnosed with a variety of conditions, including congestive heart failure (CHF), pneumonia (PN), acute myocardial infarction (AMI), chronic obstructive pulmonary disease (COPD), diabetes mellitus (DM), end-stage renal disease (ESRD), and other conditions through the Advantage Program, in which a team of nurse navigators and community health workers follow eligible patients (primarily by telephone) for 90 days post-discharge. However, this program does not address the specific needs of SUDs. Developing specialized, well-timed, targeted interventions of adequate duration and intensity built around evidenced-based approaches might be significantly more effective for patients with SUDs than embarking on a redesign of hospital system strategies. This study, conducted in collaboration with the Institute for Population Health at Temple

University Hospital, is highly significant because it will test whether an extended, Specialized Community Disease Management (SCDM) program can improve outcomes over an existing nurse navigator disease management strategy for patients with co-morbid medical conditions and SUDs.

2. Specific aim(s)

***Aim 1*:** Our core SCDM intervention will be adapted and refined with patient, provider, and stakeholder input through an active community advisory board. It will use evidence-based strategies to engage comorbid patients while in the hospital, and follow them into the community using an empirically validated telephone based treatment approach as well as contact with a trained community health worker peer specialist.

Aim 2: We will test whether SCDM can impact substance use, treatment engagement, and reduction of HIV risk, while also reducing rates of RRH. Importantly, this proposal will aim to impact rehospitalization rates for six-months, which is longer than the arbitrary CMS-designated 30 days. We will conduct a three-year, randomized controlled trial of 222 patients enrolled prior to discharge who are 1) diagnosed with CHF, AMI, PN, COPD, DM, or ESRD (hereafter referred to as the targeted medical conditions), or have a previous hospitalization within the past six months regardless of medical condition, and 2) have a SUD. We will test the following four hypotheses:

Primary Hypothesis: Patients randomized to SCDM will demonstrate larger reductions in substance use measured by urine-confirmed self-reported days using over the 6-month follow-up compared to patients randomized to TAU.

Secondary Hypothesis (a): Patients randomized to SCDM will attend more specialty substance abuse intervention and treatment sessions over the 6 month follow-up than patients randomized to TAU.

Secondary Hypothesis (b): Patients randomized to SCDM will demonstrate a) reduced HIV transmission risk behaviors, and b) greater rates of HIV testing over the 6 month follow-up than patients randomized to TAU.

Exploratory Hypothesis: Patients randomized to SCDM will experience fewer days of rehospitalization and use of acute emergency services than patients randomized to TAU.

Aim 3: We will disseminate SCDM clinical techniques and the results of the clinical trial to the scientific community, the medical community, our stakeholders, and the public.

3. Endpoint(s) to be measured

Patient variables that will be measured include drug and alcohol use and problems, intervention and treatment engagement, health and medical functioning, hospital utilization (i.e. rehospitalization), psychosocial functioning, and HIV risk. In addition, client satisfaction, implementation barriers, and treatment integrity will be measured.

4. Number of subjects to be enrolled per year and in total. These numbers should incorporate numbers screened and consented to reach enrollment.

We anticipate screening approximately 1000 patients who are referred or flagged with a potential substance use issue, and have either a diagnosis of one of the targeted medical conditions or a previous hospitalization within the past six months. We expect approximately 25% of screened patients will

meet eligibility criteria and consent to take part in the study (about 250 patients). Of those patients consented, we expect approximately 222 participants will be enrolled to participate in the study (n=111 per condition).

Year 1: We anticipate we will screen and enroll 80 participants
Year 2: We anticipate we will screen and enroll 120 participants
Year 3: We anticipate we will screen and enroll 22 participants

Additionally, approximately 12 participants from the study will be enrolled into an additional sub-study in Year 1 and complete a semi-structured interview.

5. Considerations of statistical power in relation to enrollment

The power analysis for the primary hypothesis was conducted following the recommendations of Diggle et al. for mixed effects models. Using a two-sided alpha of .05, an estimated intraclass correlation of .7 between the repeated measurements, and a 15% attrition rate by month 6, we will have 85% power to detect a moderate effect of the intervention (d = .4) with a sample size of 111 patients in each group.

6. Explain procedures that will involve the subject

As part of their treatment experience, all patients who provide informed consent will continue to receive all other standard TUH medical treatment. Enrolled participants will be **randomly assigned** to either Treatment as Usual (**TAU**) via Temple's standard Advantage program or to Specialized Community Disease Management (**SCDM**). Random assignment will be stratified by 1) severity of DSM-V SUD (Low or High) as measured by the Mini-International Neuropsychiatric Interview Plus 5.0. (MINI, Sheehan et al., 1998), 2) index medical condition (CHF or Other), and 3) frequency of previous hospital utilization (high utilizer vs. non-frequent utilizer). Hospital utilization will be considered frequent if the patient has had 5 or more hospitalizations in the past year, or 2 or more hospitalizations in the past 6 months for patients with CHF. Randomized participants will receive brief intervention and referral to SUD treatment as part of their discharge planning.

Intervention Procedures

Treatment as Usual (TAU): TUH currently has a bridge to discharge program (Advantage) which consists of a nurse navigator / community health worker team which is managed through the Institute for Population Health. Participants randomized to the TAU condition will be enrolled into this program, which lasts for 90 days post-discharge. Prior to discharge from TUH, participants will be approached by the nurse navigator (RN) or a community health worker (CHW) and will complete a brief clinical assessment concerning barriers in adhering to self-care instructions (e.g., diet, weight monitoring, medication adherence) and in complying with follow-up medical visits. If a participant is discharged from the hospital before the RN or CHW is able to meet with them, the RN or CHW will contact the participant in the community. Following discharge, the RN and/or CHW will call participants 1 to 2 times each week for 90 days to complete a brief assessment and help them problem-solve any adherence / compliance issues they have. Participants may also be visited at their home or in the community by a CHW. The CHW will assist patients to get to appointments and to survey the home environment in order to identify other outstanding issues as needed. The CHW services will be employed based on the recommendation of the RN (e.g. if the RN detects that the patient is struggling with adherence / compliance issues). The CHW will prioritize and increase the number of visits for participants that report

poor medication compliance or missed appointments. Substance misuse, addiction, and mental illness are not specifically addressed in the TUH Advantage program.

In addition to the standard TUH Advantage program described here, participants who are randomly assigned to TAU will receive one session of Brief Intervention and Referral to SUD Treatment by the study Behavioral Health Consultant (BHC) while in the hospital. If a participant is discharged from the hospital before the BHC is able to conduct an initial brief intervention session, the BHC will contact the participant in the community and complete the initial session within one week after the participant's discharge from the hospital. The intervention will be similar to the strategy described immediately below, and will include providing patients with normative feedback and encouragement to engage in SUD treatment; the BHC will work with the discharge team to find suitable referrals and work to secure an appropriate discharge plan for willing participants.

For those patients that express a need for ongoing support past 90 days, the RN or CHW may continue to provide some additional support up to 180 days to help the patient stabilize in the community. This ongoing support will include at a maximum: initiating weekly contacts in months 4 and 5 until the patient is able to transition, and possibly initiating bi-weekly contacts in month 6 if still needed. These contacts will focus on helping the patient transition to other forms of support – treatment, case management in the community, etc.

Specialized Community Disease Management (SCDM): The SCDM intervention will last for 90 days and will be administered by a Licensed Clinical Social Worker (LCSW) functioning as a Behavioral Health Consultant (BHC) trained in evidence-based brief intervention and brief treatment approaches. After enrollment in the study, the BHC will conduct 1-2 brief intervention sessions at bedside. If a participant is discharged from the hospital before the BHC is able to conduct an initial brief intervention session, the BHC will contact the participant in the community and complete the initial session within one week after the participant's discharge from the hospital. These sessions will last 20-40 minutes each, and the BHC will employ motivational enhancement treatment (MET) with targeted behavioral strategies to create a problem-centered, flexible intervention strategy for patients at various levels of readiness to change. Patients are provided with direct normative feedback based on their use level and encouraged to quit or cut down. In most cases, this will include a discussion of the patient's past efforts to quit and previous treatment attempts. The BHC will negotiate an open, modifiable goal regarding how patients would like to handle their substance use. This approach is flexible as patients who would not consider treatment or working towards abstinence can often still connect with the BHC around less stringent goals (cutting down / harm reduction). The BHC's feedback will emphasize the importance of considering and engaging in treatment.

If a patient is willing to enter treatment, the BHC will work with the hospital discharge planning team to find suitable referrals and work to secure a place in an appropriate facility. Additionally, the BHCs will explore the participant's risk for contracting HIV and determine whether the patient has been tested; participants at risk who have not been tested recently will be encouraged to be tested while an inpatient. The BHC will provide the participant with various health communication materials from our Brief Intervention Toolkit. Finally, while still inpatient, the BHC will orient the participant to the procedures of the telephone-based follow-up calls and introduce the peer CHW, who can follow-up on treatment and recovery matters with participants (see below for the full description of the CHW's role).

Following hospital discharge, the BHC will conduct follow-up phone calls with participants as a part of continuing care. The BHC will call the participant twice a week for the first four weeks following discharge, and then once a week for the next 8 weeks of the intervention. The phone calls will be about 15-20 minutes long. During the call, the BHC will conduct a brief assessment using RecoveryTrack™ (14 questions; 5-7 minutes). The BHCs will respond to elevated risk reported by the patient (e.g., frequent drug use, intravenous drug use, high cravings). On each call, the BHC will deploy one simple intervention from the Brief Intervention Toolkit with the goal of helping the patient 1) reduce risk, 2) accept the need for drug treatment and engage with it, and 3) set small goals related to risk reduction and problem solve to achieve those goals. The questions also focus on medication adherence and follow-up at

outpatient visits for medical issues. The BHC will directly handle most of the situations raised by patients regarding their medical adherence (keeping primary care visits, monitoring diet, etc.); however, should the patient's self-report indicate medical deterioration, the BHCs will involve the Temple Advantage RN in the call. In these cases, the RN will follow TUH's standard Advantage practices, as described above in TAU. If a participant enters community treatment during the 90-day SCDM intervention, the BHC will continue the follow-up phone calls on schedule to support treatment engagement and facilitate the transition.

In the SCDM condition, participants will also receive CHW support, but their CHW will be a peer in stable recovery from addiction. Based on the patient's level of risk, the BHC will dispatch the peer CHW to visit with the patient in the community. The Peer CHW will work closely with the study BHC to support patient decisions and goals around treatment engagement and harm reduction. The Peer CHW will make home and community visits (no fewer than 1 per month) and will perform such tasks as accompanying patients to treatment visits and 12-Step meetings, and surveying patients' living situations. The Peer CHW can provide encouragement and support to patients engaged in treatment, and also provide a model of a recovery lifestyle. In the event that patients discontinue calls, the SCDM team will try to reach the patient by telephone or through contacts and check in on them. To encourage patients to stay in contact with the study social worker and peer specialist, participants in the SCDM condition will receive small incentives for completing at least weekly phone calls with the SCDM clinical team. Participants must complete at least one full phone call, including a RecoveryTrack™ assessment, per week to receive the incentive. SCDM participants who maintain this level of contact will receive a $10 gift card to a retailer in the community (e.g., Rite Aid, CVS) for each of the first two weeks of the intervention, and they will receive a $5 gift card for each of the subsequent 10 weeks. These incentives will help ensure that the study social worker and peer specialist can maintain adequate contact with participants and thus effectively deliver the intervention.

For those patients that express a need for ongoing support past 90 days, the BHC and Peer CHW may continue to provide some minimal support up to 180 days to help the patient get connected to treatment and stabilize in the community. This ongoing support will include at a maximum: initiating weekly contacts in months 4 and 5 until the patient is able to transition, and possibly initiating bi-weekly contacts in month 6 if still needed. These contacts will focus on helping the patient transition to other forms of support – treatment, case management in the community, etc.

Participant Screening Procedures

Patients will be screened for the study following the procedures outlined in Item 9 below. Screened patients who meet eligibility criteria will be invited to participate in the study.

Participant Baseline Procedures

Patients will be recruited following the procedures outlined in Item 9 below. Following informed consent (described below in item 9), a Research Assistant will complete an assessment battery with participants at the bedside. As a part of this assessment, participants will provide a self-report of drug use, and complete other measures (see Participant Measures section below). We will also record the results from any urine toxicology screens conducted by Temple University Hospital at the time of participant's hospital intake. If we are not able to obtain these results (e.g. a toxicology screen was not conducted or results are incomplete), then we will ask the participant to provide a urine sample as a part of the Baseline Interview. As a part of informed consent, research staff will also collect a comprehensive Locator Form that elicits extensive contact information for the participant. Participants will be paid a $50 gift card for completing the Baseline Interview. Participants may choose to complete some of the Baseline Interview on one day, and return to complete it within one week (ideally within 48 hours). In these cases, participants will be paid $25 for completing the first half of the Baseline Interview, and the remaining $25 when they return and complete the full interview. Additionally, participants will receive a $5 gift card to a retailer in the community for each verified collateral contact they provide on the Locator

Form (up to 3 contacts, or $15 total). Research staff will attempt to contact each collateral provided on the Locator Form, and a collateral contact will be considered verified if research staff are able to establish contact with the person.

Temple University Hospital staff responsible for the patient's care (e.g., nurses, doctors, social workers) will be made aware that the patient is participating in the study so that hospital staff members do not duplicate treatment referral and case management efforts. After consent, the study social worker will insert a temporary chart flag into the patient's medical record indicating that the patient is enrolled in the study and which condition the patient is assigned to. This chart flag will be removed by hospital staff (which is standard procedure) after the patient is discharged from the hospital. During the consent process, patients will be informed that Temple staff responsible for their care will be notified that they are participating in the study and will also be notified which condition they are assigned to.

Participant Follow-up Procedures

We will complete follow-up assessment interviews with participants at 3 and 6 months after intake, as well as brief check-in calls at 1 and 2 months after intake. We will use patient-provided information on the Locator form to contact participants. If we are unable to contact the participant using Locator information, we will use contact information from the participant's TUH medical chart. Participant tracking software will be employed by the research staff to ensure that research staff are alerted when call windows open at each assessment point. Research staff will call participants at the times and numbers indicated on their Locator Form as the best time to reach them. For participants who are more difficult to reach, call times and call numbers will be alternated. Participants will also be mailed reminder notices informing them of an upcoming interview. Research staff will also attempt to contact participants via any other mechanisms that the participant consented to on the Locator (e.g. email, Facebook). For participants who are unreachable, messages will be left at all contacts that the participant consented to on the Locator Form. A postcard will also be mailed to the Locator contacts for whom the participant provided addresses to remind the participant of their upcoming appointment. Should contact persons indicate that they have lost track of the participant, research staff will search for the patient using available public search mechanisms (www.whitepages.com, etc.). If the participant still remains unreachable through all of the aforementioned methods, research staff will conduct an outreach visit to the home address that the participant provided on the Locator form. Research staff will travel in pairs when conducting home outreach and will not conduct outreach visits alone. When participants are reached, research staff will schedule the date and time of the interview, and will update the Locator Form in case the patient's contact information has changed.

Additionally, research coordinators may call a random selection of participants (up to 10%) who have completed follow-ups to 1) confirm that they completed a follow-up assessment with a research assistant, 2) confirm that they were compensated with the correct amount for the assessment, and 3) ask if they have any questions or concerns related to the study. To select participants for these check-in calls, we will randomly pre-assign each study ID number to be selected or not for the calls in an Excel spreadsheet separate from participant tracking. We will use a random number generator, and select the highest 10% of random numbers. These random checks will improve our data integrity and quality assurance procedures.

Confidentiality. We have devised IRB-approved procedures to safeguard patient confidentiality while attempting to locate participants. Research assistants will call participants from either a study provided cell phone or from TRI's office phone. TRI's calling system blocks the name "Treatment Research Institute" off of its listing, preventing the incoming phone from accessing TRI's name. If a participant registers more significant confidentiality concerns, research staff will call from blocked cell phone numbers that do not display the return number. When messages are left for the participant on recording devices or with collaterals, research staff members report that they are trying to reach the participant to complete a "health care survey" that the participant volunteered for. The postcard that will be sent to collateral contacts includes very basic language indicating that we are trying to reach the participant, and it does not include any language about substance use or participating in a research study.

The postcard will be sent to the participant at the collateral's address; it will be addressed to the participant, care of the collateral. Additional protections for patient follow-up can be found in the Human Subjects Protections section (item 11).

The 3-month and 6-month follow-up assessments will take place in-person, generally at Temple University Hospital. If the participant is not able to travel to the hospital, then we will meet them in a safe, neutral location such as a restaurant or public library, or at their home if the participant prefers. Research staff will travel in pairs when conducting an assessment at a participant's home and will not conduct these visits alone. The assessment battery will be similar to that collected at Baseline (see Participant Measures section below), and we will collect a urine sample. Participants will be provided with a payment of a $50 gift card for each of the 1-hour assessments. The 1-month and 2-month check-in assessments will be conducted over the phone. On these brief calls, research staff will ask the participants for updated locator information and will administer a 5-10 minute modified NSMOS assessment to gather basic information about hospitalizations, ER visits, and substance use in past 30 days. Participants be paid $10 via check or money order for completing each of the 1-month and 2-month calls. If a participant is incarcerated at any follow-up point, research staff will not attempt to contact the participant while incarcerated.

Participant Semi-Structured Interview Procedures

Twelve participants who complete the SCDM or TAU protocol will be invited to participate in a supplemental in-depth interview: 6 at 1 month after study enrollment (3 from each condition), and 6 at their Month 3 follow-up (3 from each condition). These participants will be asked about the acceptability of the intervention they received, and asked for recommendations on how to improve the intervention. This interview will be audio-recorded. The audiotapes will be transcribed, and all personal identifiers will be stripped from transcripts.

For the 1-month interviews, we will ask the first 3 TAU participants and first 3 SCDM participants who enroll in the study to participate in this interview. Should any participant decline, we will ask the next participant from that condition who enrolls in the study. For the 3-month interviews, we will ask the first 3 TAU participants and first 3 SCDM who complete the 3-month assessment but did not complete a 1-month interview to participate. As with the 1-month interviews, should any participant decline, we will ask the next participant from that condition who completes the 3-month assessment. Participants who agree to be interviewed will complete a separate informed consent for this portion of the study, as outlined in Item 9 below. Participants will be paid $50 for their time and travel to the interviews.

7. Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data.

Variable	Purpose	Instrument	Time Points				Completed by:		
			S	B	3	6	Patient	BHC	RA
Drug and Alcohol Problems	Screen/Urn Randomize	AUDIT, DAST-10, MINI	X					X	X
Substance Use	Primary Hypothesis	Timeline Followback , Uritox Quick Test, Medical Records		X	X	X	X		X
Intervention & Treatment Engagement	Secondary Hypothesis A	NSMOS		X	X	X	X		X
HIV Risk Reduction	Secondary Hypothesis B	HIV-RA		X	X	X	X		X
Rehospitalization	Exploratory Hypothesis	Temple Hospital Utilization Review				X			X

Patient Demographics and Medical Functioning	Covariates	ASI, Healthy Days		X	X	X	X		X
Patient Mental Health Functioning	Covariates	PHQ-9, ACES (Baseline only)		X	X	X	X		X
Satisfaction	Covariate	Client Satisfaction				X	X		X
Social Support	Covariate	MOS-SSS-6		X	X	X	X		X
Quality of Life	Covariate	Q-LES-Q-SF		X	X	X	X		X
Distress Tolerance	Covariate	DTS		X			X		X
Sensation Seeking	Covariate	BSSS		X			X		X

Screening Instruments

Alcohol Use Disorders Identification Test (AUDIT). The AUDIT (Babor et al., 2007) was developed by the World Health Organization to serve as a brief screening instrument and includes questions on frequency and alcohol problems and dependence (Allen et al., 1997, Reinert & Allen, 2002, Saunders et al., 1993).

Drug Abuse Screening Test (DAST-10). The DAST-10 (Skinner, 1982) is a 10-item face valid self-report measure of problematic substance use that is utilized for clinical screening and treatment/evaluation research and which surveys potential involvement with drugs during the past 12 months (Allen et al., 1997; Maisto et al., 2000; Saunders et al., 1993; Yudko, Lozhkina & Fouts, 2007).

DSM-V SUD Diagnosis: MINI Plus 5.0. The MINI is a short structured diagnostic interview developed in the United States and Europe for DSM-IV and ICD-10 psychiatric disorders (Sheehan et al., 1998). The MINI has become the structured psychiatric interview of choice for psychiatric evaluation and outcome tracking in clinical psychopharmacology trials and epidemiological studies. We will modify the MINI to meet DSM-V criteria for SUD. In DSM-V, the 7 DSM-IV items for dependence and 4 items for abuse have been merged into a single entity of 11 items called a "Substance Use Disorder" but with the following two changes - the abuse item of recurrent legal problems will be removed and an item for craving or strong desire to use will be added (American Psychiatric Association, 2013). A diagnosis of SUD requires 2 or more of the 11 items, and SUDs have three levels of severity: 2-3 items = mild, 4-5 = moderate, and 6+ = severe; any diagnosis of SUD results in study eligibility.

Patient Outcomes

90-Day Timeline Followback (TLFB): The TLFB (Sobell & Sobell, 1992) is a structured interview which helps patients recall their substance use to reflect a 90-day period. Patients are presented with a calendar representing the past 90 days, and the interviewer helps the patient anchor the calendar with memorable events to reconstruct their use (dates, amounts) over the designated period. *Administered at 0,3,6 months.*

Urine Toxicology Results: We will record the results of participants' urine toxicology screens from medical charts. We will record results for the following illicit substances: cocaine, opiates, amphetamines, methamphetamines, benzodiazepines, cannabis, barbiturates, PCP, and Blood Alcohol Content (BAC). *Administered at Baseline only.*

Urine testing: Urine drug testing will be done using kits that test for cocaine, opiates, amphetamines, methamphetamines, benzodiazepines, cannabis, barbiturates, and PCP. These will be purchased from ACON International. These kits provide a rapid (5-minute) on-site urine test. *Administered at 0,3,6 months.*

Non-Study Medical and Other Services (NSMOS): This questionnaire was adapted from the Treatment Services Review (McLellan et al., 1992) for patients in medical settings. The NSMOS counts substance abuse treatment, medical services, visits to medical offices, hospitalizations, and emergency room visits received that were not a part of the assigned treatment. *Administered at 0,3,6 months. Brief version administered at 1 and 2 months.*

Temple Hospital Utilization Review: TUH conducts utilization reviews on all patients discharged for the targeted medical conditions to determine whether patients experience rehospitalization and use the emergency room. This data is pulled through a pre-written algorithm which can be adjusted to pull all inpatient and ER encounters over a six-month period. The TUH Institute for Population Health will supply this data for study participants.

HIV Risk Assessment (HIV-RA): The HIV Risk Assessment provides a brief self-report measure of HIV testing history and sexual risk and uses the preceding three months as the time interval of interest. The HIV-RA was developed Lisa Bond, PhD, and David Metzger, PhD, experts in the field of HIV risk behaviors. *Administered at 0,3,6 months.*

Addiction Severity Index-6th Edition Modified Version (ASI6-Modified) . The ASI is a multi-dimensional interview used to measure the substance use, health, and social problems of those with alcohol and other drug problems, both at admission to treatment and subsequently at follow-up contacts (McLellan et al., 1992; McLellan et al., 1980). We are using an abbreviated version of the ASI-6 that eliminates many of the items that do not contribute to our primary hypotheses and takes approximately 20 minutes to complete. We will use only the ASI domains for medical, drug use, alcohol use, and psychological status for covariate analysis. The ASI-6 produces Recent Status Scores in each of these four areas, which have demonstrated high levels of inter-rater, test-retest, and concurrent reliability (Cacciola et al., 2011). *Administered at 0,3,6 months.*

Healthy Days Symptoms: The Healthy Days Symptoms Module (Newschaffer, 1998) was taken from the CDC's Health-Related Quality of Life Survey, which is part of the State-based Behavioral Risk Factor Surveillance System (BRFSS). This module measures the number of days over the past month that a patient was affected by symptoms such as pain and anxiety, as well as the number of healthy days. *Administered at 0,3,6 months.*

Patient Health Questionnaire-9 (PHQ-9). The PHQ-9 is a self-administered diagnostic screener for depression (Kroenke, Spitzer & Williams, 2001). It scores each of the 9 DSM-IV criteria for despression based on the mood module from the Primary Care Evaluation of Mental Disorders (PRIME-MD). *Administered at 0,3,6 months.*

Adverse Childhood Experiences Scale (ACES). The ACES is a self-administered scored scale that assess 10 types of childhood trauma. It was developed as a part of the Adverse Childhood Experiences Study, and has been shown to be related to adult health and mental health outcomes (Felitti et al., 1998). We have also included items from the Philadelphia Urban ACE (Public Health Management Corporation, 2013). The Philadelphia ACE expands the assessment of adverse childhood experiences to examine additional stressors that are specifically related to the urban Philadelphia community setting. *Administered at baseline only.*

Medical Outcomes Study Social Support Survey – 6 item. The MOS Social Support Survey 6-item (MOS-SSS-6) (Holden et al., 2014; Sherbourne & Stewart, 1991) is a 6-item self-administered social support survey that was developed for patients with chronic conditions. A higher score indicates more global functional social support. *Administered at 0, 3, 6 months.*

Quality of Life Enjoyment and Satisfaction Questionnaire – Short Form. The Q-LES-Q-SF (Endicott, Harrison, & Blumenthal, 1993) is a 16-item self-report measure designed to measure participant enjoyment and satisfaction experienced in various areas of daily functioning. *Administered at 0, 3, 6 months.*

Distress Tolerance Scale (DTS). The DTS (Simons & Gaher, 2005) is a 15-item self-report questionnaire in which respondents indicate the degree to which they believe they can experience and endure distressing emotional states. Lower on the DTS scores indicate a tendency to experience psychological distress as intolerable or unacceptable. Low distress tolerance has been posited to be related to substance use, suggesting that an intolerance of distress is an underlying mechanism for maintaining use (Leyro, Zvolensky, & Bernstein, 2010). DTS total score has been used as a global index of perceived distress tolerance. *Administered at baseline only.*

Brief Sensation Seeking Scale (BSSS). The BSSS is a self-report measure adapted from the 1979 Sensation Seeking Scale originally designed by Zuckerman (Hoyle et al, 2002) which attempts to capture behaviors and attitudes towards activities that are often associated with risk and/or danger, as well as the willingness to engage in dangerous activities for the sake of such thrilling (Zuckerman et al, 1993). High sensation seeking has been shown to be associated with substance use (Zuckerman et al, 1993). The BSSS has been validated for use with adult populations as well as adolescent populations (Stephenson et al, 2009). *Administered at baseline only.*

Client Satisfaction Questionnaire: The Client Satisfaction Questionnaire was developed for this study and assesses the extent to which participants perceived the intervention to be helpful and useful. It contains both closed- and open-ended questions in order to obtain information that will help us further refine the intervention for dissemination. *Administered at 6 months only.*

8. Describe characteristics of the subject population, such as their anticipated number, age ranges, sex, ethnic background, and health status. The study should employ a study design with gender and race representation appropriate to the purpose of the research. Strong justification must be provided for exclusion of broad population groups. Identify the criteria for inclusion or exclusion. Explain the rationale for the use of vulnerable populations as research subjects (i.e., prisoners, pregnant women, disabled persons, drug users, children).

Research participants will be inpatients at Temple University Hospital (TUH) in Philadelphia, PA who 1) are diagnosed with congestive heart failure (CHF), pneumonia (PN), acute myocardial infarction (AMI), chronic obstructive pulmonary disease (COPD), diabetes mellitus (DM), or end-stage renal disease (ESRD), or have a previous hospitalization within the past six months regardless of medical condition, and 2) meet criteria for a SUD by DSM-V criteria. We expect that 222 participants will enroll in the study. We will not exclude any potential participant based on race or gender, and members of gender and minority groups, the elderly, and disabled will be included in the research in the same proportion as they are represented in the populations of patients served at TUH. These patients are, on average, 35% female, 82% Black, 15% White, 3% other minorities, and 20% Hispanic. Elderly subjects and those with medical problems will be included in the research as long as they are able to give competent, informed consent and understand the content of the research instruments. Participants with disabilities will be accommodated. We will monitor gender and minority representation to ensure that it is representative of the target population, and will over-sample any gender and racial groups that are significantly under-represented.

9. Describe plans for recruitment of subjects, including advertisement and posters and the consent procedures to be followed, including the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects and the methods of documenting consent.

Prior to beginning study recruitment, we will conduct a utilization review to identify potential study participants. This review will identify patients who: 1) have been hospitalized within the past three years for one of the targeted medical conditions; and 2) have diagnostic history of a SUD in their medical record. A previous diagnosis of these conditions does not necessarily mean that the patient either currently or ever truly met criteria for these conditions. These patients will be flagged and if they are readmitted into TUH they will be assessed and if found to meet inclusion criteria, invited to participate. In addition to flagging the patients identified during the utilization review, admitted patients with a diagnosis of one of the targeted medical conditions and who have a diagnosis of SUD in their medical record will be identified through the electronic flagging system at TUH. Patients admitted to TUH who

have a previous hospitalization within the past six months and a diagnosis of SUD in their medical record will also be flagged. Additionally, the LCSW and/or RAs will identify potential patient participants on key hospital units via referral from the medical team. Flagged or referred patients will then be approached for screening by an RA. We will maintain a recruitment log that will include basic demographic information (gender, age, race, and ethnicity) for any patient approached to be in the study and will indicate whether the patient consented, refused, or was found ineligible.

Inclusion and Exclusion Criteria

Inclusion Criteria: 1) patient is 18 years or older, 2) admitted to the hospital for one of the target medical conditions or has a previous hospitalization within the past six months, 3) a screening score of at least 8 on the AUDIT, or a screening score of at least 3 on the DAST, 4) patient meets criteria for a substance use disorder as defined by DSM-V and assessed via the MINI Plus 5.0, and 5) patient reports that s/he used alcohol or drugs in the 60 days prior to his/her current hospitalization.

Exclusion Criteria: (a) the medical practitioner or BHC overrule these criteria because medical and psychiatric complications exist that would contraindicate research participation or because after questioning the patient it appears that the substance use is mild enough that further intervention is not warranted; (b) the patient was admitted to the hospital directly from a drug and alcohol inpatient rehabilitation facility; (c) the patient reports plans to leave the Philadelphia greater metropolitan area within the next 6 months; (d) the patient reports that s/he is currently homeless (i.e., s/he is living in a place not meant for human habitation, such as the street, a car, or a park); (e) the patient is not English-speaking; (f) patient has had an organ transplant; (g) patient is being discharged on a ventilator; (h) patient has a ventricular assist device or an artificial heart or (i) if the patient is unable to provide valid informed consent by correctly describing the key components of consent to the RA.

Patients who are identified as potential study participants through the processes described above will be asked to complete a screening consent with an RA. We are requesting a waiver of written documentation of consent for the screening process. According to 45 CFR 46.117(c), written documentation may be waived if "the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from breach of confidentiality." The screening consent form would be the only written document linking the patient to the research, thus a requirement for written consent would paradoxically be the only real danger to loss of privacy and confidentiality for participants who agree to be screened. We will provide an information sheet to patients prior to screening that contains informed consent information, and we will obtain verbal consent that the patient is willing to participate in the screening. For patients who consent to screening, the RA will administer the AUDIT, DAST, and MINI to determine if they meet inclusion criteria. Patients who meet the inclusion criteria and are interested in participating will be asked to provide written informed consent with an RA. Patients will be selected for the semi-structured interview via a convenience sampling procedure. For the 1-month interviews, we will ask the first 3 TAU participants and first 3 SCDM participants who enroll in the study to participate in this interview. Should any participant decline, we will ask the next participant from that condition who enrolls in the study. For the 3-month interviews, we will ask the first 3 TAU participants and first 3 SCDM who complete the 3-month assessment but did not complete a 1-month interview to participate. Participants who agree to be interviewed will complete a separate informed consent for this portion of the study.

During the informed consent process, patients will be fully informed of the procedures, the nature of the study conditions, the randomization procedure, inclusion and exclusion criteria for the study, and the compensation associated with participating in the study. They will be informed that all research data collected in the study will be kept strictly confidential, and that we have applied for or obtained an NIH Confidentiality Certificate that will shield the research data from a subpoena or court order. The only exceptions to confidentiality (clearly specified in the consent form) will pertain to information related to medical emergencies, disclosure of current child/elder/dependent abuse or neglect, or imminent risk of death or serious injury to the participant or others. Finally, these individuals will be informed of all known potential risks and benefits of participation, their right to refuse or revoke consent at any time, and

the names and phone numbers of responsible individuals they may contact for additional information or to register complaints about study procedures. They will also be asked to complete a brief consent quiz to ensure their understanding of the study requirements, the risk and benefits, and their human subject protections. All items answered incorrectly will be reviewed with the participant to ensure adequate understanding. This process will continue until participants demonstrate at least a 95% understanding of the essential elements of the informed consent document. Potential participants will then be asked if they have any questions and will be asked to sign the informed consent form to document their agreement to participate. They will receive a duplicate copy of the consent form for their records. The original signed consent form will be kept in a locked filing cabinet only accessible to staff working on this study.

10. Discuss whether risks to the subject are 'minimal' or 'greater than minimal.' List the major risks of subject participation. Describe any possible benefits of subject participation. Are the risks to subjects reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result?

The risks to subjects enrolled in this study are minimal. There are four anticipated potential risks associated for participants enrolled in this study.

1. Perception of coercion: It is possible that some participants may feel coerced to participate in the research study because a healthcare professional at the hospital told them about it.
2. Discomfort answering research questions, providing biological data, and/or being audio-recorded: Participants may experience mild and transitory psychological discomfort from completing research measures that deal with emotionally laden material or from providing urine samples. Participants in the Semi-Structured Interviews may also experience discomfort from having their interviews audio-recorded. The probability of these risks and the magnitude of the anticipated harm are likely to be small.
3. Discomfort associated with the treatment intervention: Participants may experience emotional distress given that the interventions are designed to encourage them to become more aware of their own substance use behaviors and how those behaviors may be impacting their physical and psychological wellbeing. We expect this level of distress to be similar to that which patients would experience during any psychological or psychoeducational intervention, and thus is not a function of the research participation per se.
4. Harm from Breach of Confidentiality: Participants are at risk for harm as a result of being identified as a study participant or as someone with an alcohol or drug problem. The likelihood of this occurring is small.

Benefits to participants: Participants in this study may benefit from receiving an intervention (either TAU or SCDM) which is designed to reduce the risk of rapid rehospitalization (RRH). Participants in the SCDM intervention may additionally benefit from receiving the expanded intervention which could lead them to reduce their substance use and / or seek treatment. This project will also yield considerable information on behavioral changes associated with the SCDM intervention.

Importance of Knowledge to be Gained: The aim of this project is to test the impact of an intensive Specialized Community based Disease Management (SCDM) approach to assist substance-dependent patients with medical comorbidity in reducing substance use and avoiding rehospitalization. If this SCDM approach proves to be effective, patients will demonstrate detectable reductions in substance use, higher engagement rates with specialty care, and reduced use of acute care (hospitalizations and Emergency Department visits) during the six-month follow-up period, resulting in reduced health care costs.

The risks associated with participating in this study are reasonable given the benefits and importance of knowledge to be gained.

11. Describe the procedures for protecting against or minimizing any potential risks, including physical, psychological, legal and confidentiality risks, and assess their likely effectiveness. Where appropriate, discuss provisions for insuring necessary medical or professional intervention in the event of adverse events to the subjects and for monitoring the data collected to insure the safety of subjects. Also, where appropriate, describe alternative treatment and procedures that might be advantageous to the subjects.

1. Perception of coercion: The RAs and LCSW will be trained to describe the study to eligible patients, including the risks and benefits, prior to offering an invitation to participate in the study. The RA/LCSW will clearly state that the patient's decision to participate is voluntary and that it will not impact the services they receive at the hospital. Patients will be informed that Temple staff responsible for their care will be notified that they are participating in the study and which condition they are assigned to. However, patients will be told that these individuals have no vested interest in their participation and will receive no benefit if they choose to participate. All potential participants will be told that if they feel any pressure to participate from hospital staff they can voice this concern to the PI or other TRI research staff, and the PI will discuss this matter with the TUH PI and/or other appropriate individuals.
2. Discomfort answering research questions, providing biological data, and/or being audio-recorded: Individuals enrolled in any study may experience mild and transitory emotional discomfort when answering the questions posed in interviews and on questionnaires, or providing a urine sample. All participants will be informed about these possible risks before signing the consent form. In order to minimize discomfort with providing a urine sample, the sample will not be collected under observation. The research staff will complete a training regarding monitoring and addressing emotional distress among research participants, as well as an additional training on the urine collection process which will include suggestions for decreasing participant discomfort. Participants will be told that they can choose not to respond to a question that they find upsetting and can withdraw from participation at any time without negative consequence. Participants completing an audio-recorded Semi-Structured Interview will be told that they can decline to have their interview recorded at any time.
3. Discomfort associated with the treatment interventions: Participants may experience mild and transitory psychological discomfort while participating in the treatment interventions. Drs. Brooks and Morrison will jointly train the Nurse Navigators and LCSW to monitor patient participants for distress by observing their behavior during their brief intervention sessions, as well as during check-in telephone calls. This training will focus specifically on helping patients to manage difficult feelings, screening them for potential harm to self and others, and implementing methods to help ensure their physical safety and emotional well-being. If necessary, the LCSW and Nurse Navigators can obtain timely clinical consultation about the participant's distress by contacting their clinical supervisor.
4. Harm from Breach of Confidentiality: Data collected in the study will be kept strictly confidential and will not be shared with anyone outside of the research team. The only exceptions to confidentiality, which will be clearly specified in the consent form, will be for information related to medical emergencies, current child abuse or neglect, elder abuse, or imminent risk of death or serious injury to the participant or others. If a participant tells us that s/he has been abusing a minor or elder, then we will report this to the appropriate authorities. All research materials will be coded with a research number and will contain no other identifying information. Information collected on paper (e.g., consent forms, HIPAA forms, Locator Forms) will be stored in locked filing cabinets at TUH or TRI, and computer spreadsheets will be saved in password-protected files. Participants will be assigned a study identification number which will be affixed to all collected data. Linkage between participant identity and identification numbers will be stored in a password protected electronic file available only to the PI and designated research staff. All research instruments will be computerized for this study,

and the data will be entered via the Web into a secure server located at the University of Pennsylvania's Data Management Unit. All computers have security codes and password protections to prevent unauthorized access. The Web-based RecoveryTrack™ information collected by the LCSWs as a part of the SCDM intervention will be stored in a separate secure data entry system at TRI given that it will contain identifying information (e.g., patient name). This application is "role" based (e.g., counselor, RA), allowing for assignment of specific access privileges for different users. Efforts to contact participants for telephone check-ins or follow-up appointments will make no mention of the study until it is established that the participant has been reached. Access to participants' telephone numbers, addresses, and other contact information will be limited only to research staff members who need to contact a participant for study purposes. Should any breaches of participant confidentiality occur, they will be reported to the relevant IRB (i.e. TRI and Temple), DSMB, and PCORI officials.

12. Describe procedures for reporting Serious Adverse Events (SAEs) and Adverse Events (AEs), and Unanticipated Problems. Include the definition of SAEs and AEs.

Serious Adverse Events (SAEs) will be defined as death; a life threatening event due to post-discharge health problems related to the index condition or the targeted disease (e.g. CHF, AMI, PN, COPD, DM, ESRD, or the health condition that the patient was initially hospitalized for if not one of the six previously listed conditions), suicidal behavior (i.e. serious ideation/attempt), psychiatric distress, or drug/alcohol complications/overdose. Participants in this study are substance dependent and at risk for RRH, and are thus at risk for clinical worsening. Although we do not believe the study procedures or intervention places participants at increased risk for clinical worsening (significant increase in alcohol/drug use compared to baseline), we will review and report events of clinical worsening that leads to hospitalization. A component of the study interventions involves referral to specialty treatment, including inpatient hospital-based treatment as appropriate. Admission to hospital-based inpatient substance use treatment will not be defined as an SAE unless, as noted above, it occurs as a result of or in conjunction with clinical worsening, overdose, or complications due to alcohol/drug use. Childbirth, pre-planned elective procedures, and unrelated medical events that require hospitalization will not be considered SAEs.

Adverse Events (AEs) will be defined as report of coercion to participate in the study; significant discomfort from answering research questions or providing urine samples such that the participant decides to stop their participation; significant discomfort or distress from participating in the intervention; negative side effects due to breach of confidentiality; significant increase in drug/alcohol use compared to baseline; significant increase in psychiatric symptoms compared to baseline; or significant increase in symptoms of the index medical disease. We will monitor attrition rates, but drop out from the study will not be reported as an AE. Clinically insignificant events are not considered AE's. Examples of clinically insignificant events include mild viral illness (e.g., colds, flu, and runny nose), common headaches, minor scratches, and mild symptoms or problems associated with medical conditions not related to the index condition. Participants may have medical and psychiatric problems which may continue during the course of the study. As per the definition of AEs, only significant worsening of baseline medical and psychiatric status or new problems will be reported as AEs.

All adverse and serious adverse events occurring during the study are documented on a form, reviewed and signed by the PI or Co-I and reported to TRI and other applicable IRBs. All non-fatal adverse events that meet the above definition of "Severe" are reported to the IRBs and relevant PCORI Office within 48 hours of our awareness of the event (24 hours for fatal events). A summary of all SAEs and AEs that occurred during the previous year will be including the annual progress report to the relevant IRBs.

As described below, we are collecting medical chart data, including emergency room visits and hospitalizations, from study participants for a period beginning two years prior to their enrollment in the study and ending three years after their enrollment in the study. However, since participants are actively

engaged in the study for only a 6-month period, we will not report any AEs that are discovered via chart data collection that occurred outside of the participant's period of active participation in the study. However, we will report any AEs discovered through chart data collection if they occurred during the participant's period of active engagement in the study and were not previously reported. The period of active engagement in the study will be defined as beginning with the date of consent and ending six months after the date of consent.

13. **If this study is a chart review, indicate the time frame of data to be collected (from when to when). Also, will the data be collected anonymously (meaning that only aggregate data will be collected, and there will be no names or codes maintained to match the data with the original files)?**

We will collect data from participants' medical charts at TUH as part of this study. This information will include the patient's name, health insurance status, hospitalizations, emergency room visits, diagnoses, medications, and results of urine drug tests at TUH. We will collect this information beginning on the date two years prior to the participant's study enrollment date and ending on the date three years after their study enrollment date. The data will not be collected anonymously, as we will need to link the chart data to specific participants in order to determine study outcomes. However, we will de-identify all research data collected from the charts; this data will be linked and stored under the participants' research identification numbers. All chart data will be provided to TRI by TUH.

14. **Children, defined as individuals under the age of 21, must be considered for potential enrollment in every study as subjects unless there are scientific or ethical reasons for excluding them. See below for the permissible exclusionary circumstances listed in the NIH Policy. If no exclusion applies: 1) discuss your plan for the inclusion of children; 2) justify the age range of children to be enrolled; 3) indicate the expertise of the research team with regard to children; 4) describe the facilities for the children; 5) indicate the number of children to be enrolled to give sufficient power for meaningful analysis; 6) describe how the assent process for children 7 to 17 years of age will be carried out.**

Justify your exclusion based on one of the exclusionary circumstances listed:

- The research topic is irrelevant for children
- Children are barred by law from participation because of the risk
- Study is redundant; knowledge is being obtained in another study or is already available
- Separate age-specific children study is preferable
- Rarity of disorder makes inclusion of children extremely difficult
- The limited number of available children are already enrolled in a nation-wide pediatric disease network
- Study design precludes direct applicability to children
- Insufficient adult data to judge potential risk for children
- Study design is a follow-up of an adult study

As the NIH definition of children includes all persons less than 21 years old, we will include children between the ages of 18 and 21 in this investigation. Based on census data provided by the TUH Outreach program, we expect that less than 1% of our participants will be between the ages of 18-21. We will exclude potential participants who report that they are younger than the age of 18, as this research topic is not relevant for this population. The targeted medical conditions are rare in children, and the intervention may not be appropriate for children under the age of 18 with SUDs.

15. **This study involves research to be performed at:**

[please list site(s)] Temple University Hospital
3401 N Broad St.
Philadelphia, PA 19140

Data collection and intervention procedures will be conducted at TUH. Intervention procedures involving the Community Health Worker or Peer Specialist will also be conducted throughout the surrounding community (e.g. participants' homes, 12-Step meetings, treatment programs). The Principal Investigator at TUH, Dr. Mary Morrison, will assist Dr. Brooks by providing supervision of research procedures at TUH and the surrounding community.

Reminder: It is Principal Investigator's responsibility to obtain copies of FWAs for each performance site.

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