Attachment UUU

Study title: Implementation of Cessation Treatment in Community Based Mental Health Centers

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1.1.1 Study Protocol

Title:	**Proactive Outreach for Smoking Treatment (POST)**
Drug or Device Name(s):	N/A
FDA IND/IDE	N/A
Sponsor:	NIH/NIDA
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PROTOCOL SYNOPSIS

Study Title	Proactive Outreach for Smoking Treatment (POST)
Funder	NIH/NIDA
Clinical Phase	N/A
Study Rationale	The US Public Health Service (USPHS) designated tobacco dependence as a chronic disease. This is especially true for smokers with serious mental illness (SMI) who make more cessation attempts and are less successful sustaining long-term abstinence than the general population. There is a significant health disparity wherein individuals with SMI have a higher tobacco use prevalence and a greater risk for tobacco-related mortality than the general population. Chronic care models suggest chronic disease management requires a multidisciplinary care team to assess tobacco use, administer treatment, support patient self-management, and monitor progress. Proactive telephone outreach to smokers and brief provider interventions are two effective chronic disease management strategies. Community based mental health centers (CMHCs) are a primary treatment access point for many smokers with SMI. However, rates of intervention with smoking by CMHC providers are low. In order to implement the chronic care model for tobacco dependence for CMHCs, comprehensive implementation strategies are needed.
Study Objective(s)	**Primary** • To develop an implementation strategy to implement proactive tobacco cessation treatment into community mental health treatment settings Secondary • To test the effectiveness of the implementation strategy as well as the effectiveness of a proactive tobacco cessation treatment strategy.
Test Article(s) *(If Applicable)*	The study intervention combines provider intervention about tobacco (asking patients if they use tobacco, advising patients to quit, assessing willingness to quit, assisting with quitting via counseling or medication or referral for treatment, and arranging for follow-up), and proactive outreach (calling smokers in the health system and offering treatment).
Study Design	There are 3 studies proposed in the grant. The first study consists of qualitative interviews of leadership, clinical staff, and patients at two community mental health centers. The following two studies

	will be two sequential pilot tests of the implementation strategy in two community mental health centers.
Subject Population **Key Criteria for Inclusion and Exclusion:**	Participants will be patients and employees (leadership and clinical staff) at two community mental health centers in Minnesota. Inclusion criteria for employees are to be on staff at the two community mental health center recruitment sites. There are no exclusion criteria for employees. Patient inclusion criteria include being English-speaking, current smokers (>25 days/month), patients at the community mental health center. Patient exclusion criteria includes judged by community mental health as being unable to participate in research (due to cognitive impairment or any other reason), no access to a telephone, no access to an address at which they can receive mail.
Number Of Subjects	Total Number of Subjects: Study 1: 29; Study 2: 25 patients, 33 staff; study 3: 50 patients, 200 staff Total Number at Hennepin Healthcare: 0 Total Number of Sites: 2
Study Duration	For study 1, each subject's participation will last one day, the entire study will last 3 months For study 2, each patient subject's participation will last 3 months, staff participation will last 6 months, the entire study will last 6 months For study 3, each patient subject's participation will last 15 months, staff participation will last 12 months, the entire study will last 18 months
Study Phases **Screening** **Intervention** **Follow-Up**	Study 1 potential participants will be approached for a single time point consent and qualitative interview. Study 2 potential patient participants will be approached in person or via an information letter, interested participants will complete informed consent and a baseline survey, all participants will receive and outreach attempt and may choose to enroll in counseling, participants will complete a follow-up survey 3 months post-enrollment. Some participants will be selected to participate in qualitative interviews. Study 3: potential participants will be approached, interested participants will complete informed consent and a baseline survey. 3 months later, participants will complete a second baseline survey. Participants will receive 3 outreach attempts, 3 months apart. At each outreach, participants will be given the choice of whether to enroll in counseling. Participants will complete follow-up surveys at 6, 9, and 15 months post enrollment.

Efficacy Evaluations	Study 1: Qualitative interview, Study 2: surveys at baseline and 3 months post-implementation and qualitative interviews, Study 3: participation data, surveys at 6, 9, and 15 months post-enrollment and interviews at 15 months post-enrollment
Pharmacokinetic Evaluations	N/A
Safety Evaluations	Study 1 is only a qualitative interview. If safety concerns arise during the interview, they will be documented and submitted to the IRB. Study 2 & 3: participants' mental health providers will be informed about their study participation. If participants note a worsening of their mental health symptoms, we will inform their providers, take appropriate clinical action if necessary, and evaluate whether this change is due to changes in their smoking, and report to the IRB as an adverse event.
Statistical And Analytic Plan	Interviews will be coded using deductive and inductive codes. We will then conduct a framework matrix analysis. We will summarize implementation data with respect to treatment delivery and utilization, and patient outcome data. For patient outcomes, we will explore the adjusted effects using a series of generalized linear mixed effects models adjusted for potential confounders, baseline values and clustering.
Data And Safety Monitoring Plan	DSMB

Study 1: Stakeholder Interviews

Procedures		**Pre-enrollment**	**Enrollment/interview call (day 0)**
Chart Review	Identify smokers	X	
	Obtain clearance from treatment team	X	
	Distribute study flyer to eligible participants	X	
In CMHC (or by telephone)	Consent		x
	Interview		x

Study 2: Short Pilot

Procedures		Pre-implementation (day 0-day 60)	Enrollment (day 30-90)	Implementation (Day 60-180)	End of Implementation follow-up (day 150-180)
Organizational coaching	Online training	X			
	Readiness meeting	X			
	Coaching calls	X		X	
	In-person workshop	X			
Staff training	Online training	X			
	In-person workshop/role play	X			
	Learning community	X		X	
	Performance feedback			X	
Patient recruitment and enrollment	Identify smokers	X			
	Informed consent		X		
Intervention delivery	5 A's delivered at each visit			X	
	Proactive outreach			X	
	Telephone counseling			X	
Assessment	Pre-post training evaluations	X			
	After visit surveys			X	X
	Baseline survey		X		
	3-month follow-up survey/biochemical verification				X
	Stakeholder interviews				X

Study 3: Full Length Pilot

Procedures		Enrollment/Baseline 1 (day 0-60)	Pre-implementation (day 60-90)	Baseline 2 (day 90-180)	Implementation (Day 120-300)	3-month follow-up (day 210-240)	6-month follow-up (day 300-330)	12-month follow-up (Day 390-420)
Organizational coaching	Online training		X					
	Readiness meeting		X					
	Coaching calls		X		X			
	In-person workshop		X					
	Sustainment meeting				X			
Staff training	Online training		X					
	In-person workshop/role play		X					
	Learning community		X		X			
	Performance Feedback				X			
Patient recruitment and enrollment	Identify smokers	X						
	Informed consent	X						
Intervention delivery	5 A's delivered at each visit				X			

		Enrollment/Baseline 1 (day 0-60)	Pre-implementation (day 60-90)	Baseline 2 (day 90-180)	Implementation (Day 120-300)	3-month follow-up (day 210-240)	6-month follow-up (day 300-330)	12-month follow-up (Day 390-420)
Intervention delivery								
	Proactive outreach				X			
	counseling				X			
Assessment	Pre-post training evaluations		X					
	After visit surveys	X		X	X			X
	Patient baseline surveys	X		X				
	Follow-up surveys					X	X	X
	Biochemical verification							X
	Stakeholder interviews							X

2 BACKGROUND INFORMATION AND RATIONALE

The US Public Health Service Clinical Practice Guideline (CPG) designates tobacco dependence a chronic disease because tobacco users require several interventions and make several quit attempts over their lifetimes.[1] This is especially true for smokers with SMI, who make more quit attempts and have higher relapse rates than smokers without SMI.[2-5] There is a significant health disparity among individuals with SMI wherein the smoking prevalence is between 44-66%.[5-7] Individuals with SMI die 15-25 years earlier than those without, due, in large part (64%),[8] to smoking-related disease.[9-11] Despite similar motivation to quit, the smoking prevalence among individuals with mental illness is not declining, in contrast to general population declines.[5,12-14] One explanation is that available treatments are not reaching smokers with SMI.

Chronic care management strategies are effective at reducing tobacco use. Chronic care management relies on population-based care to ensure that guideline-consistent interventions reach all patients. The chronic care model[15,16] proposes four essential chronic disease management activities: (1) periodic review of patients' disease course and management, (2) help for patients to self-manage their disease, (3) interventions to optimize disease control, and (4) continuous follow-up of patient progress. Chronic care management requires a multidisciplinary team, including individuals with behavioral treatment skills. The CPG recommends using the 5A's approach for the management of tobacco use.[1] Providers should Ask all patients' their smoking status at each visit, Advise smokers to quit, Assess willingness to quit, Assist patients in quitting, and Arrange for follow-up. "Ask" doubles the odds of abstinence, "Advise" increases abstinence by 30% and a 1-3 minute provider-delivered intervention increases patient abstinence rates by 40%.[1]

Chronic care management improves tobacco cessation treatment utilization and abstinence. Previously successful chronic care management strategies in primary care patients include electronic medical record (EMR) prompts, monthly follow-up of smokers aimed at treatment engagement following tobacco cessation treatment, and telephone care management.[15-17] Among psychiatric patients, a computerized, stage-of-change tailored, motivational intervention to promote cessation initiated during a psychiatric hospitalization and repeated twice over 6 months resulted in improvements in cessation rates over the following year, with abstinence rates increasing at each progressive follow-up time point.[18] Periodic invitations to treatment result in reductions in smoking prevalence for primary care and psychiatric patients.

Chronic care management strategies require periodic check-ins with patients to review patient progress and connect them to treatment. One well-validated strategy for chronic care management for tobacco is proactive outreach to patients to connect them to tobacco cessation treatment. Proactive outreach to patients has been found in 3 large-scale pragmatic trials to be more effective than addressing smoking solely at medical visits. In two studies conducted by Co-I Fu (preliminary studies 1&2), proactive outreach (compared to usual care) resulted in a 5-6 fold increase in cessation counseling utilization, a 2 fold increase in medication use, and a 2-6 fold increase in patients who used both counseling and medication (consistent with CPG recommendations).[19,20] A third trial in VA mental health clinics (preliminary study 3) found proactive outreach resulted in a doubling of medication utilization, a 7 fold increase in counseling utilization , a 12 fold increase in use of counseling and medication, and a doubling of prolonged abstinence rates.[21] Proactive outreach may be even better for promoting cessation in smokers with SMI than in smokers without SMI.[22] Proactive outreach is particularly important for psychiatric patients because mental health providers are reluctant to intervene with smokers and may not assess or document smoking in the EMR.[23] Proactive, continuous follow-up of patients with self-management support to quit or reduce smoking is needed for smokers with SMI.

Tobacco cessation pharmacotherapies are effective for smokers with SMI. Varenicline, bupropion and nicotine replacement therapy are efficacious for patients with schizophrenia, major depression and bipolar disorder.[24-26] However, in 2009, black box warnings for varenicline and bupropion urged monitoring for worsening psychiatric symptoms. The warnings were removed after a randomized,

placebo-controlled, clinical trial in 4116 smokers with mental illness found no safety concerns of varenicline, bupropion or the nicotine patch.[26] Dissemination of accurate information about cessation pharmacotherapy to mental health providers, who may be wary due to warnings or fear of worsening symptoms, is essential.

Tobacco cessation counseling is effective for smokers with SMI. Given high levels of dependence among smokers with SMI, and barriers to cessation success, intensive treatment including longer duration counseling is necessary.[27] With regard to cessation counseling, pilot or observational studies with smokers with SMI have found promising effects of a range of provider interventions including brief intervention,[28] motivational interviewing,[29] group therapy focused on cessation or wellness,[30-34] peer intervention,[35,36] intensive individual counseling[37] and face to face smoking cessation counseling + smoking cessation care coordination.[38] Of these approaches, brief interventions by psychiatric providers are particularly appealing for under-resourced CMHCs.

Telephone counseling is an evidence-based treatment modality for smokers with SMI. Telephone counseling has broad reach and is inexpensive per user. Quitlines are available nationwide and cost ~$1.69 per caller.[25] Quitline counseling can help smokers with psychiatric diagnoses to quit, for example,16% of Quitline callers with a psychiatric diagnosis were abstinent at 7 months post enrollment.[39] However, quit rates for callers with psychiatric diagnoses were 20% lower than those without. Telephone counseling outcomes are improved with: mental health tailoring,[40] when combined with care coordination with providers,[41] or in-person group counseling.[32] In one study, mental health tailored telephone counseling was as effective as face-to-face counseling and better attended.[42] With sufficient dose and mental health tailoring, telephone cessation counseling is highly effective. Telephone counseling and care coordination could be added to brief provider interventions to provide patients with the intensity of treatment needed for smokers with SMI.

Community mental health centers (CMHCs) are an ideal venue to implement chronic care management for tobacco dependence. CMHCs were established by the Community Mental Health Center Act of 1963, which shifted SMI treatment into the community. CMHCs provide comprehensive mental health treatment, including medication management, case management and counseling. For patients with SMI, CMHCs could be a better place to implement proactive, chronic care management for tobacco dependence than primary care. CMHCs represent the primary treatment access point for SMI patients. They comprise a comprehensive treatment team including psychiatric prescribers, case managers, and counselors. Psychiatric prescribers see their patients more often than primary care providers and are better equipped to adjust psychiatric medications following cessation.[43] Case managers can ensure patients fill smoking cessation prescriptions and maintain reliable telephone access for telephone counseling. Counselors can reinforce behavioral changes to promote abstinence. These supports are not always available in primary care. However, mental health providers have the lowest rates of intervention with tobacco use of any healthcare providers.[40,44] Among psychiatrists, rates of intervention with tobacco use are declining.[23] The administration of smoking cessation treatment is especially low in CMHCs (only 30% of providers discuss smoking with at least half their patients annually and providers report low confidence in providing cessation interventions).[45-47] Provider barriers include: undervaluing tobacco addiction as a problem, lack of knowledge of evidence-based treatment, lack of self-efficacy to change patient behavior, competing priorities, and required cross-discipline collaboration.[33,48,49]

Implementing smoking cessation treatments that adhere to a proactive, chronic care model, requires a comprehensive implementation strategy that addresses provider and organizational barriers. In other treatment settings, strategies that have been effective in implementing tobacco cessation programs include provider education, performance tracking and feedback, clinical reminders, note templates, and incentives for meeting performance goals.[50-54] Multi-modal strategies are more effective than single strategies.[54]

Scant research has studied effective strategies to promote the implementation of comprehensive smoking cessation treatment among behavioral health providers. A pre-post knowledge test showed increased knowledge of smoking cessation treatment following a mental health provider training

program.[33] A pilot implementation trial (N=304) in 6 CMHCs increased mental health providers' use of the 5 As for tobacco cessation.[28] This implementation strategy included didactic training (for both staff and psychiatrists) and access to ongoing external coaching from a physician clinic liaison. This strategy was associated with a significant increase in patient receipt of 5A's at the 6- and 12-month follow-up assessments, and increased smoking abstinence rates among patients at the 12-month follow-up. Another model, the Addressing Tobacco Use Through Organizational Change Model (ATTOC) has shown promise in substance use treatment facilities. This model includes: a 3-day on-site consultation, 3-day off site staff training, identification and training of tobacco treatment specialists, and ongoing phone consultation for 6 months.[55] Following implementation, ATTOC resulted in more favorable staff and patient beliefs toward tobacco dependence treatment, increased utilization of nicotine replacement therapy and increased receipt of smoking cessation counseling during the substance abuse treatment program.[56] Finally a pre-post trial of academic detailing and decision support resulted in increased smoking cessation medication prescriptions and a decreased population smoking rate.[57]

There are several limitations of prior implementation approaches with regard to promoting the implementation of tobacco use chronic care models in CMHCs. First, the ATTOC model requires an initial 3-day on-site consultation as well as extensive off-site training for tobacco treatment specialists: this level of training may be difficult for resource constrained CMHCs. Second, no prior implementation approaches have included ongoing performance feedback on the agency's implementation process. Multiple experimental studies have supported didactic training combined with ongoing performance feedback and coaching as the most effective staff training approach, relative to self-study or selected components (e.g., didactic training only, didactic + feedback, didactic + coaching).[58-60] Third, prior implementation strategies have been tailored to specific types of providers such as mental health specialists or substance use treatment providers. A chronic care model requires use of a multidisciplinary team, suggesting that the implementation strategy needs to be flexible enough to meet the needs of a variety of stakeholders (i.e., psychiatrists, case managers, social workers, etc.). Fourth, because only one previous pilot study has tested the effect of an implementation strategy on patient outcomes, the effects of the prior implementation strategies on smoking cessation in psychiatric patients are not well understood.[28] Finally, the focus of prior implementation strategies has been on early phases of the implementation process (i.e., preparation and implementation), with less of an explicit focus on strategies to promote long-term sustainment. Thus, implementation strategies are needed that can be adapted for low resource settings and multidisciplinary teams, that consider both implementation and patient outcomes, and that include performance feedback and strategies to promote sustainment.

To build upon the implementation strategies in prior studies, we have partnered with the New England Addiction Technology Transfer Center (ATTC), one of 14 SAMHSA funded regional centers charged with training front-line behavioral health treatment providers in evidence-based practice (of which Co-I Becker is director). The New England ATTC developed a comprehensive, theory-driven implementation strategy called the Science to Service Laboratory (SSL), which consists of three key components based on the extensive research on staff training: 1) didactic training, 2) performance feedback, and 3) coaching. A robust body of experimental literature has demonstrated that the combination of these three specific strategies is an effective implementation approach, and is more effective than any of the elements in isolation.[58-60] Each component of the SSL is sufficiently flexible that it can be tailored to meet specific contextual factors, while retaining core features. For instance, with regard to performance feedback, the approach requires that providers receive external, ongoing feedback on their delivery of the target evidence-based intervention. However, the content, duration, frequency, and delivery model of specific performance feedback sessions can be tailored to meet the needs of different stakeholders and settings. There is a substantial literature demonstrating that performance feedback improves provider behavior.[61] Feedback is most effective when: it is delivered by someone of influence, includes goals and action plans, it focuses on a problem where there is room for improvement, and recipients are non-physicians.[62] The SSL has been rolled out in 5 states

in New England to help agencies implement evidence-based interventions, and staff have reported satisfaction with the approach.[63,64] Additionally, Co-I Becker and colleagues[65] found that substance use treatment agencies that received the SSL had 3.6 times greater odds of adopting an evidence-based substance use intervention (i.e., contingency management) than agencies that received training as usual (Preliminary study 5). The proposed study will be the first to adapt the SSL model to promote the implementation of a comprehensive smoking cessation intervention and to meet the unique needs of CMHCs. Despite being widely used, the SSL has been completely untested outside of specialty addiction settings. The proposed study will tailor the SSL to make it maximally beneficial. Results can easily be fed back into ATTC with great benefit.

2.1 Name and Description of Investigational Product or Intervention

Proactive outreach. Will consist of outreach calls with the offer of a connection to counseling.

Outreach calls. Consistent with a chronic care approach, proactive outreach will be conducted by the tobacco treatment case manager. Outreach will follow the 5 A's approach. The aims of the outreach are to: (1) increase motivation to stop or reduce smoking, (2) improve self-efficacy, (3) facilitate participation in evidence-based treatment. Participants will be offered mental health tailored tobacco cessation counseling delivered by the case manager or connection to local tobacco cessation programs. In addition, the case manager will discuss tobacco cessation medication options and coordinate with the participants' prescriber and case manager to facilitate receipt of medication.

Counseling. The counseling protocol is tailored to psychiatric patients. Up to 7 counseling sessions per round of counseling will be offered using a motivational interviewing style to enhance motivation and cognitive behavioral therapy skills. Counseling will be conducted by phone, secure video visit, or in person (participant preference).

Provider intervention will include every provider administering the 5A's at every visit. Patients who are interested in cessation support will be referred to the tobacco treatment case manager for behavioral treatment and, if the provider can prescribe, be offered a prescription for tobacco cessation pharmacotherapy.

2.2 Findings from Non-Clinical and Clinical Studies

N/A

2.3 Selection of Drugs and Dosages

N/A

2.4 Relevant References

2.5 Compliance Statement

This study will be conducted in full accordance of all applicable Hennepin Healthcare Research Policies and Procedures and all applicable Federal and State laws and regulations. All episodes of noncompliance will be documented and reported according to the Prompt Reporting Guidelines, Attachment EEE, of the Hennepin Healthcare IRB Policies and Procedures.

The investigators will perform the study in accordance with this protocol, will obtain consent and assent, unless waiver of consent or other alteration is approved, and will report unanticipated problems involving risks to subjects or others and SAEs in accordance with The Hennepin Healthcare IRB Policies and Procedures and all Federal requirements. Collection, recording, and reporting of data will be accurate and will ensure the privacy, health, and welfare of research subjects during and after the study.

3 STUDY OBJECTIVES

The overall purpose of this study is to develop an implementation strategy for a proactive tobacco cessation intervention.

Aim 1: Adapt an evidence-based implementation strategy to CMHCs.

Aim 2: Pilot test the implementation strategy

Aim 3: Conduct a pilot trial to assess the feasibility, acceptability and initial effectiveness of both the implementation and intervention strategies.

4 INVESTIGATIONAL PLAN

4.1 General Schema of Study Design

Study 1 is a qualitative interview study to help assess the needs of community mental health centers in terms of tobacco cessation and to get feedback on proposed study materials/design.

Study 2: Is a pre-post pilot trial with the main aim to test the feasibility and acceptability of study procedures.

Study 3: is a pilot trial to test the feasibility, acceptability, and preliminary effectiveness of the intervention and implementation strategies.

4.1.1 Screening Phase and Baseline Assessment

Study 1: CMHC staff. Staff will be recruited during staff meetings, and from informational emails from medical directors. Directors will give the study a list of staff members who are willing to participate. Study staff will call and obtain verbal informed consent. CMHC patients. Case managers will review a list of potential patient participants (identified via chart review). Case managers will give a study flyer to participants who qualify and interested patients will contact the study. Study staff will call interested patients to schedule an in person interview at the community mental health center or a phone interview. Prior to the interview interview, we will obtain written or online, informed consent and conduct the interview. Interviews will be audio recorded.

Studies 2&3: leaders from each community mental health center have agreed to participate. These leaders will provide deidentified administrative data describing each organization. Providers who are interested in participating in the training will be recruited during provider meetings and informal emails from medical directors. Prior to the training, providers will receive a study fact sheet and a baseline survey. Completion of the survey and/or attending the trainings and/or coaching calls will be considered consent to participate. Patients will be given a flyer about the study or will receive a letter introducing the study with the opportunity to opt out. Patients will be contacted by a study staff member to assess interest and, if interested, complete written or electronic, informed consent and the baseline survey.

4.1.2 Study Intervention

Study 1: There is no intervention. This is a qualitative study only.

Study 2: The organization will participate in an implementation intervention, 6 months in duration, that consists of an in-person, hands-on training workshop, performance feedback based on anonymous patient surveys and/or electronic mental record data, and coaching calls. Organizational leaders will also participate in a series of planning meetings. Study staff will work with site leadership to develop templated language for documentation of the 5 A's in the electronic health record. Providers will be given handouts on smoking cessation resources, smoking cessation medications, and a tool to help guide them through the 5 A's. The workshop will cover the importance on intervening with people with serious mental illness about smoking in mental health treatment

settings, available treatments, documentation, and how to do the 5 As. We will make arrangements for lunch to be provided during the workshop.

The patient intervention will consist of providers discussing tobacco with patients during their visits using the "5 A's" to ask the patient about their tobacco use, advise tobacco users to quit, assess readiness to quit, assist patient in quitting by providing counseling, medication, or a referral, and arranging for follow-up. In addition, 25 patients who consented to the study will receive outreach to discuss their tobacco use and offer to help them obtain smoking cessation medication through their existing providers and also to provide ongoing counseling (up to 7 counseling sessions by phone, secure video, or in person). Outreach may also be done in person in the context of routine clinical care if the participant prefers it.

Study 3: The organizational intervention is the same as in study 2, except the implementation support will last for 9 months, and leaders will participate in a sustainment meeting at the end of the implementation to form a plan to sustain the intervention once implementation support is removed.

The patient intervention is the same except that 50 patients will receive 3 outreach attempts, over 9 months, each with an invitation to help the patient connect with treatment.

4.1.3 Part 2 (Use an appropriate descriptor such as "Open-Label Treatment")

All participants will receive the study interventions.

4.1.4 Follow-up

Study 1: there is no follow-up.

Study 2: Provider behavior will be monitored for 3 months via anonymous patient surveys and/or via electronic mental record review. 5-6 CMHC staff members will participate in qualitative interviews at the end of the implementation period (6 months post implementation). Interviews will be audio recorded.

Patients will complete one follow-up survey, 3 months post-enrollment. Abstinent participants will also complete a CO reading. This may be done during a visit to the clinic, a home visit, or via a mailed CO device. 5-6 participants will also participate in qualitative interviews. Interviews will be audio recorded.

Study 3: Provider behavior will be monitored monthly via anonymous patient surveys and/or through medical record review. Patients will be followed at 3, 6, 9, and 15 months post-implementation launch. 5-6 patients and 5-6 CMHC staff will also participate in qualitative interviews. Interviews will be audio recorded.

4.2 Allocation to Groups and Blinding

N/a

4.3 Study Duration, Enrollment and Number of Sites

4.3.1 Duration of Study Participation

Study 1: participation is 1 day

Study 2: CMHC staff will participate for 6 months, patients will participate for 3 months

Study 3: CMHC staff will participate for 12 months, patients will participate for 15 months.

4.3.2 Total Number of Study Sites/Total Number of Subjects Projected

Study 1: Study procedures will be conducted by Hennepin Healthcare Research Institute staff, but will recruit from 2 community mental health centers (Central Minnesota Mental Health Center and Lee Carlson Center).

Study 2: Study procedures will be conducted by Hennepin Healthcare Research Institute staff and two staff members from Lee Carlson Center.

Study 3: Study procedures will be conducted by Hennepin Healthcare Research Institute staff and two staff members from Central Minnesota Mental Health Center.

4.4 Study Population

4.4.1 Use of Vulnerable Populations and Patients Who Opt Out of Research

We are recruiting patients at community mental health centers because these patients have a very high tobacco use rate and a very high incidence of tobacco-related mortality. We will exclude people who are decisionaly impaired by first having their treatment providers determine if they are able to provide consent for a research study and also by verifying that the patients understand the consent form by asking them several questions about what they have read in the consent form before allowing them to consent. Of note, just because a patient has a documented mental illness does not necessarily mean that they are decisionaly impaired. Many people living with mental illness live independently and make their own legal and healthcare decisions.

3.5 Inclusion and Exclusion Criteria

3.5.1 Inclusion Criteria

Inclusion criteria for patients: daily cigarettes smokers (smoking >25 days/month), English speaking, patient in one of the two community mental health center study sites. Inclusion criteria for providers/staff: must be staff member at one of the community mental health center study sites.

3.5.2 Exclusion Criteria

Exclusion criteria for patients: cognitive impairment, judged by community mental health center staff as unable to participate in research, no access to a telephone, no address at which they can receive mail. There are no exclusion criteria for providers

5 STUDY PROCEDURES

5.1 Screening Visit and Baseline Assessment

Study 1: CMHC staff will be recruited during provider meetings, and from informational emails from medical directors. Directors will give the study a list of providers who are interested. Study staff will call and obtain verbal informed consent. We will ask the case managers to review a list of potential patient participants (based on chart review). CMHC Patients. Case managers will inform the study team whether patients would be able to participate in stakeholder interviews. Case managers will give out flyers to eligible patients. Eligible patients will contact the study to schedule an in-person interview at the community mental health center, or a phone interview. Written or online, informed consent will be obtained prior to the interview. If the patient is unable to come to an in person visit, we will mail the informed consent form to the patient with a self-addressed, stamped envelope or email or text them a link to the REDCap consent form. When we call the patient for their interview, study staff will go through the consent form with the patient using a script. The patient will take a quiz on what they have read. If the patient would like to use paper consent, we will ask them to take a picture of the signed consent form page and text or email it to study staff prior to the interview. We will then ask them to mail the signed consent form back to the research team in a self-addressed, stamped envelope provided. If the patient chooses to complete consent online, they will digitally sign in REDCap.

Study 2: Studies 2&3: leaders from each community mental health center have agreed to participate. These leaders will provide deidentified administrative data describing each organization. Providers who are interested in participating in the training will be recruited during provider meetings and informal emails from medical

directors. Providers will be given a fact sheet and told that if they complete the survey, participate in trainings or coaching calls, that they will be considered to have consented to that activity. Patients will be given a flyer about the study, or mailed a letter and a flyer and patients who receive the letter/flyer will be contacted by the smoking cessation case manager or other study staff member to assess interest and, if interested will schedule a phone, video visit, or in person visit to complete written or electronic, informed consent and the baseline survey via redcap or paper (patient preference).

5.2 Study Intervention

Study 1 does not have an intervention.

Studies 2 & 3 have an implementation strategy for providers and an intervention delivered by clinic staff directly to the patients.

Studies 2 & 3:

Implementation strategy for the health system:

The organization will participate in an implementation intervention, 3 months in duration for study 2 and 9 months in duration for study 3, that consists of a hands-on virtual or in person training workshop, performance feedback based on anonymous patient surveys given once/month and/or aggregate electronic medical record data, and coaching calls. The workshop will be video recorded and will be available to providers to watch following the training if they could not attend due to scheduling, or if they want to refer back to the workshop. Organizational leaders will also participate in planning meetings (study 2 & 3) and an end of study sustainment meeting (study 3). Study staff will work with site leadership to develop templated language for documentation of the 5 A's. Providers will be given handouts on smoking cessation resources, smoking cessation medications, and a tool to help guide them through the 5 A's. The workshop will cover the importance on intervening with people with serious mental illness about smoking in mental health treatment settings, available treatments, documentation, and how to do the 5 As.

Patient intervention:

Proactive outreach. Will consist of outreach attempts with the offer of a connection to counseling.

Outreach calls. Consistent with a chronic care approach, proactive outreach will be conducted by the tobacco treatment case manager. In study 2, the case manager will make one outreach call per participant. These outreach attempts may be conducted via telephone, HIPAA secure video calls, or at an in person visit (participant preference). Each outreach attempt will include five call attempts per available telephone number. In addition, if the participant agrees to receive texts, the participant will receive up to 5 outreach text messages. If the participant is in active clinical care, the tobacco cessation case manager can also offer to see the participant in person following a regularly scheduled appointment to discuss their smoking. In study 3, the case manager will make 3 outreach attempts, each 3 months apart. The aims of the outreach are to: (1) increase motivation to stop or reduce smoking, (2) improve self-efficacy, (3) facilitate participation in evidence-based treatment. Participants will be offered mental health tailored tobacco cessation counseling delivered by the case manager or connection to local tobacco cessation programs. In addition, the case manager will discuss tobacco cessation medication options and coordinate with the participants' prescriber and case manager to facilitate receipt of medication.

Counseling. The counseling protocol is tailored to psychiatric patients. Participants will engage in up to 7 counseling sessions using a motivational interviewing style to enhance motivation and cognitive behavioral therapy skills. Counseling sessions will be timed based on the participant's readiness to quit, such that more sessions will take place surrounding quit dates. Counseling will be done by phone, secure video visit, or in person (participant preference).

Provider intervention will include every provider administering the 5A's at diagnostic assessment and treatment planning visits. Patients who are interested in cessation support will be referred to the tobacco treatment case manager for behavioral treatment and, if the provider can prescribe, be offered a prescription for tobacco cessation pharmacotherapy.

5.2.1 Study procedures and visits study 1

Study 1: Patients will provide written or online, informed consent prior to the interview and complete the interview in person or by phone. CMHC staff will be given the option of participating by phone or in person and will therefore provide oral consent. Interviews will take 30-60 minutes.

4.2.2 Study Procedures and visits study 2

Patients.

Enrollment. Patients will provide written, or online, informed consent. They will then complete a baseline survey. Following the baseline survey, they will be called and texted for an outreach call, conducted by a smoking cessation case manager, on staff at the community mental health center. If participants prefer, the outreach session can be conducted via secure video visit or in person. At the outreach session, they can elect to enroll in smoking cessation counseling and/or get help from the case manager to reach out to their providers to obtain smoking cessation medication.

Follow-up. Three months post-baseline, patients will complete a follow-up survey online or by phone. Participants reporting abstinence will complete an expired breath CO test either conducted with a portable CO monitor mailed to the participant, a home visit, or an in-person clinic visit. At the end of the study, 5-6 patients will be selected to complete a qualitative interview.

Providers.

Training. Providers will receive a study fact sheet and baseline survey prior to the trainings. Completion of the baseline survey or attendance at the trainings will be considered consent to participate. Providers will complete a recorded, online training via Zoom or an in-person training regarding providing smoking cessation interventions to patients. This training will be attended by investigators from Brown University (Sara Becker, Sarah Helseth) who will edit training videos for future site use. An IAA will be obtained before Brown investigators participates in research activities. Providers will then have the opportunity to participate in coaching calls for 3 months. Providers will receive monthly performance feedback about smoking cessation interventions from anonymous patient surveys or aggregate medical record data for 3 months in study 2 and 9 months in study 3. Leadership for the organizations have already agreed to participate. Leaders will participate in a readiness meeting at the beginning of the study (study 2 and 3), and a sustainment visit at the end of the implementation period (study 3 only). We will work with the site to create the following implementation tools: handouts about community smoking cessation resources, handouts about smoking cessation medications, decision aids to complete the 5 As, templated language to put in electronic health record notes.

Assessment. Providers will complete a readiness assessment before and after the in-person training. We will also assess provider performance from brief, anonymous patients after visit surveys or aggregate electronic medical record data. In patient surveys, beginning the month prior to implementation, the community organization will add study surveys to their pre-existing after-visit surveys electronically about whether their provider completed each of the 5 A's (ask, advise, assess, assist, & arrange). At the end of the study, 5-6 providers will be selected to complete a qualitative interview.

4.2.3 Study procedures and visits study 3

Patients.

Enrollment. Patients will provide written or electronic, informed consent. They will then complete a baseline survey. At the time of the provider training, they will complete a second baseline survey. Following the second baseline survey, the smoking cessation case manager will begin an outreach attempt (phone, text, or in person). During the outreach, they can elect to enroll in smoking cessation counseling and/or get help from the case manager to reach out to their providers to obtain smoking cessation medication. Outreach attempts will be repeated at 3 months, and 6 months following the second baseline survey.

Follow-up. Participants will complete additional follow-up surveys at 3, 6, and 12 months following the second baseline survey. Follow-up surveys will be completed by phone or via an online survey. Participants who report abstinence at the 12-month follow-up will be asked to complete a mailed or in-person CO test. 5-6 patients will participate in a qualitative interview.

Providers will receive a study fact sheet and baseline survey prior to the trainings. Completion of the baseline survey or attendance at the trainings or coaching calls will be considered consent to participate. Providers will complete a recorded, online training via Zoom or an in-person training regarding providing smoking cessation interventions to patients. This training will be attended by investigators from Brown University (Sara Becker, Sarah Helseth) who will edit training videos for future site use. Providers will then have the opportunity to participate in coaching calls for 9 months. Providers will receive performance feedback about smoking cessation interventions from patient surveys or electronic health record data starting at the second baseline through 9 months post implementation. Leadership for the organizations have already agreed to participate. Leaders will participate in a virtual or in person site visit at the beginning of the study. 5-6 employees will participate in a qualitative interview. We will work with the site to create the following implementation tools: handouts about community smoking cessation resources, handouts about smoking cessation medications, decision aids to complete the 5 As, templated language to put in electronic health record notes.

5.3 Concomitant Medication

N/A

5.4 Rescue Medication Administration

N/A

5.5 Subject Completion/Withdrawal

Subjects may withdraw from the study at any time without prejudice to their care or their employment. They may also be discontinued from the study at the discretion of the Investigator for lack of adherence to study treatment or visit schedules, and AEs. The Investigator or the Sponsor may also withdraw subjects who violate the study plan, or to protect the subject for reasons of safety or for administrative reasons. It will be documented whether or not each subject completes the clinical study. If the Investigator becomes aware of any serious, related adverse events after the subject completes or withdraws from the study, they will be recorded in the source documents and on the CRF.

5.5.1 Early Termination Study Visit

N/A

6 STUDY EVALUATIONS AND MEASUREMENTS

Study 1: A qualitative interview guide will be sent for review to IRB before the qualitative interviews are administered. The interviews will explore: (1) tobacco cessation treatment needs, (2) barriers to treatment engagement, (3) barriers to treatment delivery, (3) the treatment protocol, (4) the training protocols, (5) recruitment strategies, and (6) the measurement protocol.

Study 2 & 3: A qualitative guide will be sent for review to IRB before the qualitative interviews are administered.

Patient Assessments.

Demographics We will assess patient demographics including gender, race/ethnicity, and age.

Tobacco use history. We will assess tobacco use history including number of cigarettes per day, years of smoking, use of other nicotine/tobacco products, prior use of tobacco cessation treatments (counseling and medication).

Fagerstrom test for Nicotine Dependence. the Fagerstrom Test for Nicotine Dependence is a 6-item measure of tobacco dependence.

The Biener Contemplation Ladder is a single item measure of readiness to quit smoking.

Use of tobacco cessation treatment. Patients will be asked if they have participated in tobacco cessation counseling of any kind (in-person, telephone, or group counseling), or if they have received or used any of the 7 FDA-approved tobacco cessation medications.

Abstinence. Patients will be asked if they have smoked in the last 7 days, and the last 30 days, if they have made an at least 24 hour quit attempt since the last assessment, and the Biener contemplation ladder.

Client Satisfaction Questionnaire. The Client Satisfaction questionnaire is an 8-item measure of health program acceptability.

Expired Air Carbon Monoxide. Expired air carbon monoxide will be measured using a bedfont smokerlyzer.

Implementation measures.

Feasibility will be measured by the percent of providers who: attend the online and in person trainings, complete role plays, attend coaching calls, and receive performance feedback. For patients, feasibility will be measured by the proportion of patients who enroll in the study, the proportion who accept proactive outreach and the proportion who complete the follow-up.

Acceptability. Qualitative interviews with 5-6 patients and 5-6 providers will be conducted at the 3-month follow-up (study 2) and 15 months post-enrollment (study 3). Interviews will be conducted by a trained research staff member. Interviews will contain open ended questions about treatment (for patients) and implementation (for providers and leaders) acceptability, burden, and suggestions for improvement. Interviews will be audio recorded. An interview guide will be submitted to the IRB prior to administering the interviews.

Effectiveness. Implementation Effectiveness will be evaluated by the proportion of patients who receive the 5As and the proportion who report using smoking cessation counseling and medication measured 3-months (study 2) or 12 months (study 3) after the start of the implementation period (assessed via patient report).

Readiness to deliver cessation treatment. This is a 25-item questionnaire measuring smoking cessation resources available to the provider, barriers to providing cessation services, cessation intervention behavior, and confidence in providing cessation treatment.

Organizational Readiness for Change. Responses to this scale reflect the extent to which the organization has the skill, training, time and resources to implement guideline consistent tobacco cessation treatment.

6.1 Screening and Monitoring Evaluations and Measurements

6.1.1 Medical Record Review

Each organization will pull a list of active patients who are English-speaking, smokers from their medical record. Case managers or providers for each patient will verify if the patient is appropriate to participate in research (without cognitive impairment, capable of providing informed consent, has a telephone and an address).

6.2 Efficacy Evaluations

Feasibility will be measured by the percent of providers who: attend the online and in person trainings, complete role plays, attend coaching calls, and receive performance feedback. We expect the majority (>75%) of providers and leaders to attend the trainings and receive performance feedback. For patients, feasibility will be measured by the proportion of patients who enroll in the study, the proportion who accept a proactive outreach and the proportion who complete the follow-up. Previous studies (preliminary studies 1-3) using this recruitment strategy have yielded a 30-44% response rate to the enrollment invitations, 62-71% for the proactive call, and 66-74% for follow-up assessment.[19,20] Results in this range would be considered feasible.

Acceptability. Patients will complete the 8-item Client Satisfaction Questionnaire (CSQ) during the follow-up assessment. Qualitative interviews with 5-6 patients and 5-6 providers will be conducted at the 3-month follow-up (study 2), and 15 month follow-up (study 3). Interviews will be conducted by a trained research staff member. Interviews will contain open ended questions about treatment (for patients) and implementation (for providers and leaders) acceptability, burden, and suggestions for improvement.

Effectiveness. Implementation Effectiveness will be evaluated by the proportion of patients who receive the 5As and the proportion who report using smoking cessation counseling and medication measured 3-months after the start of the implementation period (study 2) and at 3, 6, and 12 months post baseline 2 (study 3) assessed via patient report. Patient Effectiveness will be measured by carbon monoxide (CO)-confirmed 7-day point-prevalence from tobacco post-intervention (3 months for study 2 and 12 months from second baseline for study 3). Secondary patient outcomes will include: 30-day point-prevalence abstinence, the number of self-reported ≥24 hour quit attempts and reductions in smoking via cigarettes per day.

6.3 Safety Evaluation

We will monitor adverse events if they are reported by the patient. The study does not provide any medications or devices, so we expect there to be few adverse events reported by patients.

7 STATISTICAL CONSIDERATIONS

Qualitative analysis. Using a structured debriefing form, post-interviews notes will be written at the end of each interview and reviewed by all co-investigators. Interviews will be transcribed and deidentified. Transcription will be completed by Landmark Associates Inc. We will develop analytical codes using an iterative method in which interview notes are reviewed to: 1) consider whether the qualitative agenda is appropriate and complete, and 2) develop an initial coding structure. Deductive codes will be drawn from the interview questions (e.g., treatment needs); review of the interview notes will also allow the creation of inductive codes which capture emergent concepts from the interviews. Investigators and trained study staff will code the transcripts. Each transcript will be independently coded by two coders, who will meet to resolve discrepancies. Final codes will be entered into NVivo qualitative data analysis software. We will conduct a framework matrix analysis[66] to identify the most effective ways to organize the content and logistics of implementation strategy and pilot study design and will help guide our pilot study protocol.[66,67]

Quantitative Analysis. As a preliminary step, CMHC, provider, and patient-level characteristics will be summarized at baseline. Differences between CMHC's will be tested using graphical methods, non- parametric, and parametric tests as appropriate (e.g., Wilcoxin rank-sum test for skewed data, t-tests for normally distributed continuous data & chi-squared tests for categorical data). Consistent with Aim 3, feasibility and acceptability will be assessed as follows: feasibility will be measured by the percent of providers who attend the online and in person trainings, complete role plays, and receive performance feedback. Implementation will be considered feasible if at least 75% of providers and leaders attend the trainings and receive

performance feedback. For patients, feasibility will be measured by the proportion of patients who enroll in the study, the proportion who accept a proactive outreach and the proportion who complete the follow-up. The study will be considered feasible if results are in the range of those found in preliminary studies: 30-44% response rate to the enrollment invitations, 62-71% for the proactive call, and 66-74% for follow-up assessment (See Preliminary Studies Section). Acceptability will be assessed based on the 8 item Client Satisfaction Questionnaire (CSQ) during the follow-up assessment, as well as qualitative interviews at the 12-month follow-up. Interviews will contain open ended questions about treatment (for patients) and implementation (for providers and leaders) acceptability, burden, and suggestions for improvement. The treatment will be considered acceptable if ≥ 80% of participants respond that they are at least somewhat satisfied with their participation. Average acceptability scores will be reported. Initial effectiveness will be evaluated with respect to both implementation and patient outcomes. First, we will summarize CMHC-level implementation data with respect to treatment delivery and utilization (e.g., proportion of patients receiving each of the 5A's, using smoking cessation counseling and medication) and compare across centers. Next, baseline, 3-, 6-, and 12-month patient cessation outcomes (7-day PPA and number of quit attempts), will be summarized among the aggregate sample and by CMHC. We will explore the adjusted effects using a series of generalized linear mixed effects models adjusted for potential confounders, baseline values and clustering.[68] Models allow for flexible distribution of the outcome (binary, count) and adjust standard errors for the clustered nature of the data (clustered by provider within CMHC). Models will include a random effect for CMHC and will further adjust for potential confounders (including variables that might differ between CMHC's). Similar models can be used to test the effects on secondary outcomes (e.g., cigarettes per day) during the post-implementation period (3-, 6- and 12-months) adjusting for baseline, and to explore the effect of implementation at the patient level (use of counseling and medication) and at the provider level (SSL dose) as a predictor of primary and secondary cessation outcomes.

7.1 Primary Endpoint

For study 2, the primary end point is 3 months post-implementation. For study 3, the primary end point is 12 months post-implementation (~15 months post-first baseline).

7.1.1 Safety Analysis

All subjects entered into the study at Visit 1 will be included in the safety analysis. The frequencies of AEs by type, body system, severity and relationship to study intervention will be summarized. SAEs (if any) will be described in detail. AE incidence will be summarized.

7.2 Sample Size and Power

Sample size considerations. The proposed sample size was estimated in order to have sufficient power to assess feasibility and acceptability as well as estimate initial effectiveness, within the confines of a pilot study. We propose to enroll 50 patients and 18-27 providers as part of the Aim 3 pilot study.[69] With a two-sided alpha-level of 0.05, we will have more than sufficient power (>80%) to assess feasibility and accessibility and within-subjects effects in the small-medium range, f^2=.08.

8 STUDY MEDICATION (DRUG, DEVICE, OR OTHER STUDY INTERVENTION)

8.1 Description

Patient intervention:

Proactive outreach. Will consist of outreach attempts with the offer of a connection to counseling.

Outreach. Consistent with a chronic care approach, proactive outreach will be conducted by the tobacco treatment case manager. In study 2, the case manager will make one outreach attempt per participant. Each outreach will include five call attempts per available telephone number plus 5 text messages, participants can also be approached in person as part of routine care if the participant prefers. In study 3, the case manager will make 3 outreach attempts, each 3 months apart. The aims of the outreach are to: (1) increase motivation to stop or reduce smoking, (2) improve self-efficacy, (3) facilitate participation in evidence-based treatment. Participants will be offered mental health tailored tobacco cessation counseling delivered by the case manager or connection to local tobacco cessation programs. In addition, the case manager will discuss tobacco cessation medication options and coordinate with the participants' prescriber and case manager to facilitate receipt of medication.

Counseling. The counseling protocol is tailored to psychiatric patients. Participants my participant in up to 7 counseling sessions using a motivational interviewing style to enhance motivation and cognitive behavioral therapy skills. Counseling sessions can take place by phone, by secure video visit, or in person (participant preference).

Provider intervention will include every provider administering the 5A's at diagnostic assessment and treatment planning visits. Patients who are interested in cessation support will be referred to the tobacco treatment case manager for behavioral treatment and, if the provider can prescribe, be offered a prescription for tobacco cessation pharmacotherapy.

8 SAFETY MANAGEMENT

8.1 Clinical Adverse Events

Clinical adverse events (AEs) will be monitored throughout the study.

8.2 Adverse Event Reporting

Unanticipated problems related to the research involving risks to subjects or others that occur during the course of this study and SAEs will be reported to the IRB in accordance with IRB Attachment EEE: Prompt Reporting Guidelines. AEs that are not serious but that are notable and could involve risks to subjects will be summarized and submitted to the IRB at the time of continuing review.

8.3 Definition of an Adverse Event

An adverse event is any untoward medical occurrence in a subject receiving a test article and which the occurrence does not necessarily have a causal relationship with the treatment. An adverse event can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of the test article, whether or not related to the product.

All AEs (including SAEs) will be noted in the study records and on the case report form with a full description including the nature, date and time of onset, determination of non-serious versus serious, intensity (mild, moderate, severe), duration, causality, and outcome of the event.

8.4 Definition of a Serious Adverse Event (SAE)

An SAE is any untoward medical occurrence that:

- results in death,
- is life-threatening,
- requires inpatient hospitalization or prolongation of existing hospitalization,
- results in a persistent or significant disability/incapacity, or

- is a congenital anomaly/birth defect.

8.4.1 Relationship of SAE to study drug or other intervention

The relationship of each SAE to the study intervention will be characterized using one of the following terms: certain, probable/likely, possible, unlikely/unrelated, or unassessable.

8.5 IRB/IEC Notification of SAEs and Other Unanticipated Problems

The Investigator will promptly notify the IRB of all internal (occurring in subjects enrolled at this site) unanticipated problems involving risks to subjects or others, and Serious Adverse Events that are related to the research activity. Reports will be submitted to the IRB in accordance with the timeline below. External (at other sites) SAEs that are both unexpected and related to the study intervention will be reported promptly.

Category of Prompt Report	Initial Notification
Internal (occurring in subjects enrolled at this site), related (or more likely related than unrelated) SAE	5 days
Internal, unrelated SAE	30 days
External SAE and AEs need not be reported unless it represents an unanticipated problem	A brief summary of important AEs may be reported at time of continuing review
Unanticipated Problems Involving Risks to Subjects or Others	5 days

8.5.1 Follow-up report

If an SAE has not resolved at the time of the initial report and new information arises that changes the investigator's assessment of the event, a follow-up report including all relevant new or reassessed information (e.g., concomitant medication, medical history) will be submitted to the IRB. The investigator is will ensure that all SAE are followed until either resolved or stable.

8.6 Investigator Reporting of a Serious Adverse Event to Sponsor

The investigator will report all SAEs to the sponsor according to their reporting guidelines.

8.7 Medical Emergencies

The study is a behavioral intervention to help people stop smoking. In general, smoking is associated with improvements to health. The main concern is that the patient participants have serious mental illness and may experience a symptom exacerbation during the study. There is no evidence indicating that participation in this trial will worsen depression or cause suicidality. In fact, other studies have found that quitting smoking is associated with improvements in psychiatric symptoms.[44,70] However, given that participants will have serious mental illness, it is likely that some participants will experience worsening of depression during this study. A minority of participants may experience episodes of suicidal ideation. Thus, we will monitor and respond to these issues in an ethically sensitive manner.

As part of the community-based mental health center, all patients will have at least one mental health provider. As part of the consent, the participants will agree to allow study staff to contact their psychiatric providers to inform the providers that their patient is enrolled in a smoking cessation study and could experience symptom exacerbation or require adjustments in medication dose. Participants will also agree to have study staff contact these providers in case of symptom exacerbation. If a

participant reports active suicidality as part of counseling sessions, the tobacco treatment case manager (who will be a mental health professional who is on staff at the CMHC) will conduct a suicide risk assessment as would be done during routine care and take appropriate action.

If a participant reports any acute risk issues during follow-up contacts, the research assistant will be trained to conduct a risk assessment using a scripted assessment tool. If the participant is in imminent danger, the RA will immediately call 911 and the page Dr. Japuntich (or covering provider). In all other cases, following the RA risk assessment, Dr. Japuntich (or covering provider) will then conduct her own risk assessment. If the participant expresses suicidal thoughts, but no plan or intent, Dr. Japuntich will express empathy, urge the participant to talk to their mental health providers about their symptoms, give the participant appropriate emergency numbers and tell the patient that he or she should present to the ER if they are feeling unsafe. If the participant expresses active suicidal intentions or plans (i.e., any recent suicidal attempts, suicidal gestures, or self-injurious behavior; any current plan or intent to engage in suicidal or self-injurious behavior) to any study staff at any time point, Dr. Japuntich (or covering provider) will express concern for their safety, ask the participant to present to the nearest ER, and, if needed, 911 will be called. Any time the suicidality protocol is triggered, the participant's mental health care team will be informed, regardless of the level of suicidality. For all participants who express suicidality, Dr. Japuntich (or covering provider) will call them to follow-up by phone to follow-up as often as is needed, until we have received confirmation from their care team that the team is aware of the risk and that the participant is under their care.

9 STUDY ADMINISTRATION

9.1 TREATMENT ASSIGNMENT METHODS

N/A this is a pre-post study where all participants receive the intervention.

9.2 Data Collection and Management

All data and records will be safeguarded according to the policies of the IRB and HIPAA. All participant records and assessment data from this study will be treated as confidential, including participant names and the fact they are participating in the study. All electronic data will be stored on secure, password protected servers. A file will be maintained that associates the subject's name with that subject's study identification number. This file will be kept in a secure, password-protected file, separate from the actual study data (e.g., screener and survey data). Paper forms will be stored in locked file cabinets in a locked room. Long-term storage of these paper files will be at a facility that specializes in the storage of medical/research information. The destruction date of these files will be at least 7 years from the termination of the study and will be authorized by the PI. No identifiable data will be used for a future study without IRB approval.

Only the Principal Investigator, co-Investigators, and study staff will have access to data. The data not be used for purposes other than conducting the study. The data entry system will require login identification and passwords in order to gain access to the data. All data are considered part of the subject's confidential record. All staff will receive ethics training and will be trained by the PI in strict confidentiality procedures.

Every effort will be made to ensure that missing data are kept to a minimum. Data entry programs with range checking and response validation will be used for any data keypunched. Where appropriate, validation and range rules will be applied to the actual entry fields. The PI and statistician will conduct error checking procedures and preliminary analyses on all data to ensure their accuracy. All data designated as primary outcome data will be subject to a 100% cross-referencing. All data files are automatically backed- up daily. All audits will be supervised and documented by the PI.

Only the Principal Investigator will give permission for the release of aggregated study data. No identifiable data will be released. Participants in the proposed research will be informed, during consent, that completely de-

identified data (i.e., data that has been cleaned of all 18 types of HIPAA identifiers) will be available to other qualified researchers. Within 18 months of study completion, we will make datasets available to interested investigators who submit a written request to the PI. The only contingency on the use of the data will be that ethical guidelines be followed (e.g., only individuals who have completed a research ethics training course will have access to the data, the data will be stored securely). The NIH will be notified of transmissions of the data to interested investigators.

9.4 Regulatory and Ethical Considerations

9.4.1 Data and Safety Monitoring Plan

Monitoring.

IRB. The IRB will initially approve the study and will provide ongoing monitoring throughout the study to ensure participant safety. All needed changes or amendments to the IRB approved protocol will be submitted to the IRB in a timely manner. There will be no changes enacted in the protocol until IRB approval of the new protocol is received.

Dr. Japuntich will report all adverse events to The IRB within IRB reporting guidelines. The funding institution will be informed in cases when any significant action is taken as a result of an adverse event or by direction of the IRB. Any serious adverse event (SAE), whether or not related to study intervention, will be reported to both the IRB and the funding institution. A summary of the SAEs that occurred during the previous year will be included in the annual progress reports to both the IRB and the funding institution.

Data safety monitoring board (DSMB). Because the study involves multiple clinical recruitment sites and the recruitment of participants with SMI, a DSMB is required. We will convene a DSMB who will consist of 4 clinician investigators with expertise in serious mental illness and/or tobacco dependence. At least one member of the DSMB will be from outside the PI's home department.

The purpose of the DSMB will be to ensure the safety of the participants and to make recommendations about whether to continue, amend, or terminate the study based on the safety data. Due to the pilot nature of the trial, the DSMB will not have a large focus on efficacy.

The DSMB will meet quarterly via teleconference throughout the study. The board will also be convened at any point if unexpected safety concerns arise. The study statistician will be a non-voting member of the DSMB. Prior to trial launch, the DSMB will review the study protocol, characteristics of the study data collection sites, inclusion/exclusion criteria, definition of participants (e.g., screened, enrolled, treated, drop out, lost to follow-up), the intervention manual, rules for discontinuation of participation, outcome measures, and sample size. During enrollment, the DSMB will review reports of study admission data (number approached, enrolled, reasons for ineligibility, demographic characteristics, and retention data), protocol compliance (expected vs. actual recruitment rate, study drop-outs and reason, data quality assurance report, case report forms, protocol deviations/violations, missing data, subject refusal to provide data), and safety data (adverse events, serious adverse events). At the end of each meeting, the DSMB will submit a report documenting a review of study data and make recommendations with respect to study progress and need for modification. This report will be transmitted to the IRB and to NIDA.

Data.

All data and records will be safeguarded according to the policies of the IRB. As reviewed above, all participant records and assessment data from this study will be treated as confidential, including participant names and the fact they are participating in the study. All electronic data will be stored on secure, password protected servers. A file will be maintained that associates the subject's name with that subject's study identification number. This file will be kept in a secure, password-protected file, separate from the actual study

data (e.g., screener and survey data). Paper forms will be stored in locked file cabinets in a locked room. Long-term storage of these paper files will be at a facility that specializes in the storage of medical/research information. The destruction date of these files will be at least 7 years from the termination of the study and will be authorized by the PI.

Only the Principal Investigator, co-Investigators, and study staff will have access to data. The data entry system will require login identification and passwords in order to gain access to the data. All data are considered part of the subject's confidential record. All staff will receive ethics training and will be trained by Dr. Japuntich (PI) in strict confidentiality procedures.

Every effort will be made to ensure that missing data are kept to a minimum. Data entry programs with range checking and response validation will be used for any data keypunched. Where appropriate, validation and range rules will be applied to the actual entry fields. The PI and statistician will conduct error checking procedures and preliminary analyses on all data to ensure their accuracy. All data designated as primary outcome data will be subject to a 100% cross-referencing. All data files are automatically backed- up daily. All audits will be supervised and documented by the PI.

Only the Principal Investigator will give permission for the release of aggregated study data. No identifiable data will be released. Participants in the proposed research will be informed, during consent, that completely de-identified data (i.e., data that has been cleaned of all 18 types of HIPAA identifiers) will be available to other qualified researchers. Within 18 months of study completion, we will make datasets available to interested investigators who submit a written request to the PI. The only contingency on the use of the data will be that ethical guidelines be followed (e.g., only individuals who have completed a research ethics training course will have access to the data, the data will be stored securely). The NIH will be notified of transmissions of the data to interested investigators.

Education/Training.

All research personnel connected with this project will participate in mandatory education in human research subject protection. At the core of the self-directed training program is the tutorial provided through the Collaborative Institute Training Initiative (CITI) hosted by the University of Miami. All staff must complete online training in the protection of human research subjects and units specific to HIPAA regulations and compliance. To be certified, all staff must pass the CITI training every 3 years and the HIPAA unit annually. All investigators and staff on the present application have been certified and will maintain certification.

9.4.2 Risk Assessment

Potential Risks.

Nicotine withdrawal symptoms after quitting: There is a strong likelihood that most study participants who quit smoking will experience some nicotine withdrawal symptoms, including anxiety, restlessness, anger, irritability, sadness, problems concentrating, appetite change and weight gain, insomnia, and decreased heart rate. Generally, these reactions are temporary and pose no serious health risks.

Worsening of psychiatric symptoms and emergent suicidality. Available evidence suggests that quitting smoking has not been associated with increases in psychiatric symptoms among those with mental illness and may even result in improvement in psychiatric symptoms.[44,70] However, this population is at high risk for acute psychiatric episodes.

Confidentiality or loss of privacy. We will collect potentially sensitive information about participants; if released inappropriately, participants may experience embarrassment or distress. The seriousness of the consequences would depend on the nature of the information revealed and to whom the information was revealed. Given the numerous steps we take to protect participant confidentiality, we think the risk of a breach of confidentiality is low.

Discomfort or distress when completing assessment and treatment procedures. Some participants may feel uncomfortable or distressed answering personal or private questions during assessment or treatment. In our previous studies, when individuals do report discomfort in these situations, it is mild. Participants will be informed at the beginning of each assessment that their participation is voluntary and they may refuse to answer any questions that make them uncomfortable or withdraw from the study at any time.

ADEQUACY OF PROTECTION AGAINST RISK

Recruitment and Informed Consent

Prior to proactive recruitment of participants, we will obtain approval from their treatment team to ensure that they are appropriate for the study and capable of consent. Written or online informed consent (including a description of the nature, purpose, risks, and benefits of the study) will be obtained from participants before initiating study procedures. The voluntary nature of the study and the participant's right to withdraw at any time will be stressed in the consent materials. Patients will be encouraged to call the study staff with any questions about the study prior to signing the consent form.

Protections Against Risk

Minimization of nicotine withdrawal symptoms after quitting: Participants that decide to use cessation medication will be told that it will reduce but not entirely eliminate withdrawal symptoms. Participants will be instructed to call their outpatient physician or psychiatrist in the case of severe withdrawal reactions. Withdrawal

symptoms typically abate within 1 to 2 weeks of quitting and are not medically dangerous.

Minimization of loss of confidentiality/privacy: All data and records will be safeguarded according to the strict privacy/confidentiality policies of The Hennepin Healthcare Institutional Review Board (IRB). Confidentiality will be maintained by numerically coding all data, disguising identifying information, and keeping data in secure electronic locations or locked in file drawers. All electronic data will be numerically coded and stored on a limited access server in a secure research space. All paper forms will be stored in locked file cabinets in a locked room. Names of participants will be stored separately. Participant information will be accessible only to research staff, who are pledged to confidentiality and complete training in the ethical conduct of research (i.e., both HIPAA and CITI trainings). Dr. Japuntich will also personally train staff on maintenance of participant confidentiality. Identifying information will not be reported in any publication.

Minimization of discomfort or distress when completing assessment and treatment procedures: We will take two specific steps to reduce the possibility of discomfort or distress:

Study will be clearly explained. A detailed explanation of the study, including what study participation would involve, the nature of the questions participants will be asked to answer, the nature of measurements, the nature of the intervention being tested, and the right to withdraw from the study at any time without penalty, will be provided to the participants, in writing (through the informed consent form). Participants will be encouraged to ask questions about the study. Individuals who are uncomfortable answering these types of questions, assessments, or interventions likely will not choose to participate. Those who choose to participate but are very uncomfortable with the questions, assessments or interventions will be told that they can refuse these assessments or choose to withdraw from the study.

Staff Training. All staff interacting with participants will be trained by Dr. Japuntich to ask questions and complete assessments in a sensitive manner and be supportive to any participant experiencing discomfort or distress.

Minimization of risk from worsening of depression and emergent suicidality. There is no evidence indicating that participation in this trial will worsen depression or cause suicidality. In fact, other studies have found that quitting smoking is associated with improvements in psychiatric symptoms.[44,70] However, given that participants will have serious mental illness, it is likely that some participants will experience worsening of depression during this study. A minority of participants may experience episodes of suicidal ideation. Thus, we will monitor and respond to these issues in an ethically sensitive manner.

As part of the community-based mental health center, all patients will have at least one mental health provider. As part of the consent, the participants will agree to allow study staff to contact their psychiatric providers to inform the providers that their patient is enrolled in a smoking cessation study and could experience symptom exacerbation or require adjustments in medication dose. Participants will also agree to have study staff contact these providers in case of symptom exacerbation. If a participant reports active suicidality as part of counseling calls, the tobacco treatment case manager (who will be a licensed mental health

professional who is on staff at the CMHC) will conduct a suicide risk assessment as would be done during routine care and take appropriate action.

If a participant reports any acute risk issues during follow-up contacts, the research assistant will be trained to conduct a risk assessment using a scripted assessment tool. If the participant is in imminent danger, the RA will immediately call 911 and the page Dr. Japuntich (or covering provider). In all other cases, following the RA risk assessment, Dr. Japuntich (or covering provider) will then conduct her own risk assessment. If the participant expresses suicidal thoughts, but no plan or intent, Dr. Japuntich will express empathy, urge the participant to talk to their mental health providers about their symptoms, give the participant appropriate emergency numbers and tell the patient that he or she should present to the ER if they are feeling unsafe. If the participant expresses active suicidal intentions or plans (i.e., any recent suicidal attempts, suicidal gestures, or self-injurious behavior; any current plan or intent to engage in suicidal or self-injurious behavior) to any study staff at any time point, Dr. Japuntich (or covering provider) will express concern for their safety, ask the participant to present to the nearest ER, and, if needed, 911 will be called. Any time the suicidality protocol is triggered, the participant's mental health care team will be informed, regardless of the level of suicidality. For all participants who express suicidality, Dr. Japuntich (or covering provider) will call them to follow-up by phone to follow-up as often as is needed, until we have received confirmation from their care team that the team is aware of the risk and that the participant is under their care.

9.4.3 Potential Benefits of Trial Participation

Potential benefits for all participants include improved treatment engagement with the potential to increase the likelihood of smoking cessation, which could in turn prevent smoking related morbidity and mortality as well as improve the effectiveness of psychiatric medications. By participating in the research, all participants will also benefit from knowing they may ultimately be helping others as they will have helped us test an implementation strategy. The costs of participating in the research will be minimized through our extensive efforts to maintain confidentiality, reduce discomfort or distress, and minimize medical complications.

9.4.4 Risk-Benefit Assessment

Overall, it is expected that the potential benefits to participants in the proposed study will outweigh potential risks.

9.5 Recruitment Strategy

Study 1: Providers will be recruited during provider meetings, and from informational emails from medical directors. Directors will give the study a list of providers who are interested. Study staff will call and obtain verbal informed consent. We will ask the case managers to review a list of potential patient participants (based on chart review). Case managers will give out flyers to eligible patients. Eligible patients will contact the study to

schedule an in-person interview at the community mental health center or a telephone interview. Prior to the interview, we will obtain written, informed consent and conduct the interview.

Studies 2&3: leaders from each community mental health center have agreed to participate. Providers who are interested in participating in the training will be recruited during provider meetings and informal emails from medical directors. They will receive a study fact sheet prior to trainings. Completion of the baseline survey or attendance at the trainings or coaching calls will indicate consent to participate. Patients will be given or mailed a flyer about the study and information about how to opt out and patients who do not opt out will be contacted by the smoking cessation case manager in the clinic to complete written or electronic, informed consent and the baseline survey.

9.6 Informed Consent/Assent and HIPAA Authorization

9.6.1 Waiver of Consent

For study one, providers will provide verbal consent for interviews that take place over the phone. Interviews are minimal risk. Providers are unlikely to have time to do an in-person interview. Conducting the interview by phone will increase participation rates. No PHI will be collected during the interview. We will give the providers a fact sheet with pertinent study information prior to agreeing to participate. The waiver will not affect the rights and welfare of the subjects.

For study 2 and 3, we will ask patients to complete anonymous surveys about whether their provider completed the 5 A's. Participants will be given a fact sheet. Completion of the survey will serve as consent.

9.6.2 Waiver of Assent

N/A

9.6.3 Waiver of HIPAA Authorization

We would like a waiver of HIPAA authorization to allow the organization to conduct chart reviews to identify potentially eligible participants (English-speaking tobacco users). The study will not obtain this list, but rather these participants will be approached by clinic staff and given a flyer or mailed a letter about the study.

9.7 Payment to Subjects

9.7.1 Reimbursement for travel, parking, and meals

None.

9.7.2 Payments to subject for time, effort, and inconvenience (i.e. compensation)

In study 1, participants will be paid $20 to complete interviews. Payment for in-person interviews will be in cash, payment for telephone interviews will be by gift card.

In study 2, patient participants will be paid $20 per assessment. There are two assessments, so participants will be paid a total of $40. Participants who report abstinence at the 3-month

assessment will be paid an additional $20 to complete an in-person CO test. In addition, 5-6 patients and 5-6 providers will complete qualitative interviews, for which they will be paid $20.

In study 3, patient participants will complete 5 assessments, and will be paid $20 per assessment. Participants who report abstinence at the final assessment will be paid an additional $20 to complete an in person CO test. In addition, 5-6 patient participants and 5-6 staff will complete interviews and will be paid $20.

9.7.3 Gifts

none

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