Promoting Evidenced-Based Tobacco Smoking Cessation Treatment in Community Mental Health Clinics

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Protocol – Promoting Evidence-Based Tobacco Cessation Treatment in Community Mental Health Clinics

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1. Abstract

a. Provide no more than a one page research abstract briefly stating the problem, the research hypothesis, and the importance of the research.

Tobacco smoking is the single largest contributor to premature mortality among persons with serious mental illness (SMI).[1,2] An estimated 53% of US adults with SMI – six million individuals – smoke tobacco,[3] compared to 15% of US adults overall.[4] Overall US smoking rates have declined dramatically over the past 50 years, but smoking has persisted at consistently high rates among those with SMI.[5] The vast majority of persons with SMI who smoke would like to quit,[6] and combination pharmacotherapy and behavioral counseling is effective and safe for people with SMI,[7-10] increasing abstinence rates up to 7-fold over behavioral counseling alone.[8,11] Provision of effective evidence-based smoking cessation treatment could reduce substantially the premature mortality experienced by people with SMI, however few in this group receive evidence-based treatment.[12-15]

In two large Maryland healthcare systems, fewer than 5% of persons with schizophrenia who smoke are prescribed evidence-based smoking cessation pharmacotherapy;[13,14] limited available research shows similarly low rates in other states.[12,15] Rates of behavioral smoking cessation counseling are also low.[16] As many people with SMI receive the majority of their healthcare in the specialty mental health sector,[17-19] it is critical to increase mental health providers' delivery of evidence-based smoking cessation treatment. Strategies to achieve this goal will need to overcome knowledge and self-efficacy barriers among mental health providers, including skepticism that people with SMI want to quit smoking, misperceptions about cessation treatment efficacy and safety for this group, and low self-efficacy to deliver evidence-based smoking cessation treatment for consumers with SMI.[12,20-23] Mental health providers may also perceive smoking cessation treatment as outside their scope of practice.[12,20-23] Clinic-level barriers to treatment, such as lack of systems for assessing smoking status and willingness to quit among consumers with SMI, may also need to be addressed.[20,21] No published studies have evaluated implementation strategies to increase mental health providers' delivery of evidence-based smoking cessation pharmacotherapy and counseling for people with SMI.

This is a R34 pilot study funded by NIMH as part of the Johns Hopkins NIMH P50 Center to Accelerate Translation of Interventions to Decrease Premature Mortality in Series Mental Illness. This is a pilot study to assist and study the implementation of evidence-based smoking cessation treatment in community mental health clinics in Maryland over 12 months. In this study, we will develop and test an implementation intervention designed to improve mental health providers' knowledge, self-efficacy and delivery of evidence-based smoking cessation treatment. The implementation intervention includes both synchronous and asynchronous training modules, including using an avatar practice module for motivational interviewing skills, a tobacco smoking identification and cessation protocol, expert consultation, coaching and organizational strategy meetings. The study is guided by Gurses et al.'s interdisciplinary framework of clinicians' compliance with evidence-based guidelines.[24]

The study will result in a set of training and implementation tools and resources for community mental health clinics to address tobacco smoking. Results also will inform the future design of a large-scale trial testing strategies to increase delivery of evidence-based smoking cessation treatment for SMI in community mental health settings.

2. Objectives

The specific aims are:

Aim 1: To inform implementation intervention development, examine barriers to evidence-based smoking cessation treatment in community mental health clinics serving consumers with SMI.

1. What do providers in a community mental health organization perceive as the key barriers to delivery of evidence-based smoking

cessation treatment, and what strategies could help to overcome these barriers?

Aim 2: Assess the implementation intervention's effects on providers' knowledge, self-efficacy, and delivery of evidence-based smoking cessation treatment and preliminary measures of consumers' abstinence from tobacco smoking. The intervention will:

1. Increase providers' knowledge of smoking cessation treatment for consumers with SMI.
2. Increase providers' self-efficacy to deliver evidence-based smoking cessation treatment.
3. Increase providers' delivery of the four key components of evidence-based smoking cessation treatment: assessment of smoking status & willingness-to-quit, pharmacotherapy prescribing, and behavioral counseling.
4. Increase abstinence from tobacco smoking among consumers with SMI.

Aim 3: Assess the acceptability, appropriateness, and feasibility of the implementation intervention to increase delivery of evidence-based smoking cessation treatment:

1. The implementation intervention will be perceived as acceptable, appropriate, and feasible by community mental health clinic providers.

3. Background (briefly describe pre-clinical and clinical data, current experience with procedures, drug or device, and any other relevant information to justify the research)

Persons with serious mental illness (SMI) have a mortality rate three times higher than those without SMI,[2,25-27] primarily due to cardiovascular disease (CVD),[28-31] and tobacco smoking is the single largest contributor to CVD and premature mortality in this population.[1,2] Fifty-three percent of US adults with SMI smoke tobacco,[3] compared to 15% of US adults overall.[4] Smoking prevalence is highest among adults with schizophrenia, with estimates of >60%.[32] Smoking cessation has significant benefits: after one year of abstinence from tobacco smoking, risk of myocardial infarction is reduced by 50%, and smoking cessation in mid-life eliminates 90% of smoking-related mortality risk.[33,34] Combination pharmacotherapy (3 efficacious options are available: varenicline, bupropion or nicotine replacement therapy (NRT)) and behavioral counseling is effective cessation treatment for smokers with SMI,[7-10] but estimates suggest that fewer than 5% of smokers with SMI receive pharmacotherapy,[12-15] and rates of behavioral counseling – which, alone, is not effective cessation treatment for smokers with SMI[10] – are also low (≈12%).[16]

Research shows modifiable knowledge and self-efficacy barriers to mental health providers' delivery of evidence-based smoking cessation treatment.[12,20-23] While 65-80% of smokers with SMI want to quit,[6] in a recent study 77% of mental health providers believed smokers with SMI are not interested in quitting.[22] Providers' disproven but persistent concerns that cessation may increase SMI symptoms and/or disrupt psychotropic medication regimens and their uncertainty about the safety of smoking cessation pharmacotherapy may also impede treatment.[12,22] In 2009, case reports[35-37] of adverse psychiatric side effects led to black box warnings on varenicline and bupropion. These warnings were removed in December 2016 after cohort and clinical trial evidence showed no increased risk of adverse psychiatric events among people with SMI.[8,13,14,38] While few mental health providers feel comfortable delivering cessation treatment, they report high willingness to do so if they were to receive training.[22] Mental health clinic-level barriers, including lack of systems for assessing and tracking consumers' smoking status and willingness-to-quit, may also need to be addressed.[20,25]

Few mental health providers deliver evidence-based smoking cessation treatment and many mental health clinics lack standard systems for screening, monitoring, and treating tobacco smoking.[12,22] Community mental health settings are often under-resourced and providers face multiple competing demands and smoking cessation has not historically been an organizational priority. As noted above, mental health providers may face knowledge and self-efficacy barriers that impede their delivery of evidence-based smoking cessation treatment.[12,20-23] Nonetheless, mental health providers' extensive experience working with consumers with SMI makes them optimally positioned to deliver effective cessation treatment for tobacco smoking, the leading cause of premature mortality among people with SMI.

4. Study Procedures

a. Study design, including the sequence and timing of study procedures (distinguish research procedures from those that are part of routine care).
b. Study duration and number of study visits required of research participants.

Currently this protocol is being submitted as a study where all study procedures are delivered remotely. If and when COVID-19 restrictions are lifted, we may submit a petition to have some of the study activities in-person as appropriate.

Overview: We will work with 5 community mental health clinics in Maryland. This project's goal is to implement evidenced-based tobacco smoking cessation treatment in community mental health clinics serving the population of persons with serious mental illness. Tobacco smoking cessation treatment involves behavioral counseling and pharmacotherapy. The main outcome of the project is the utilization of 4 evidence-based practices in the clinic setting: 1) screening for tobacco use in all patients, 2) an assessment of willingness to quit for those who smoke, 3) referral and utilization of behavioral counseling for those interested in cutting down or quitting smoking, 4) receipt of pharmacotherapy for those interested in cutting down or quitting smoking. The community mental health clinics are already providing some treatment for smoking cessation for their patients. The evidence-based practices in this project are within their scope of practice. The implementation intervention is 12 months.

Study sites and participants: We plan for five community mental health clinics in Maryland to participate in this study. The clinics serve populations with serious mental illness. Participants for data collection and the implementation intervention will be employees of the community mental health organization including leaders, mental health providers (psychiatrists and/or nurse practitioners, licensed counselors, psychologists, social workers), primary care providers and other staff. We estimate N=120 employee participants across the five sites. Employees may take part in different parts of data collection, depending on their role in the clinic. Patients with serious mental illness seen in the clinic are also study participants as their data will be analyzed.

Description of Implementation Intervention: The multicomponent implementation intervention is designed to improve providers' knowledge, self-efficacy and delivery of evidence-based smoking cessation treatment for smokers with SMI. The intervention includes training on evidence-based smoking cessation treatment, including an innovative online avatar motivational interviewing practice module; a tobacco smoking identification and cessation protocol; expert consultation for prescribers and therapists; coaching; and organizational strategy meetings. A more detailed description of each component is outlined below.

Tobacco smoking identification and cessation protocol: Our team has developed a tobacco smoking identification and cessation protocol to assist providers in delivering evidence-based smoking cessation treatment. This protocol includes a resource guide that provides an overview of the IMPACT study and will help clinicians navigate their work on the project, a manual for delivering smoking cessation behavioral counseling sessions and pharmacotherapy, and willingness-to-quit guides to help facilitate brief smoking cessation conversations based on patient responses to the tobacco smoking status and willingness-to-quit assessment.

Expert consultation: Expert consultation will be available for prescribers and therapists to discuss issues and ask questions related to smoking cessation pharmacotherapy and behavioral counseling. Study team members who are experts in smoking cessation pharmacotherapy and behavioral counseling will be available during the 12-month intervention to conduct as-needed phone or email consultation with smoking cessation medication prescribers and therapists providing smoking cessation behavioral counseling.

Coaching: Coaching will be available for providers to discuss specific patient cases and develop smoking cessation behavioral counseling skills. Coaching will be offered monthly (via Zoom/phone) for one hour in groups at each site and as needed individually, with the expectation that providers attend at least one session per quarter. Coaching sessions will take a case management approach, focusing on overcoming barriers to providing evidence-based smoking cessation treatment.

Organizational Strategy Meetings (OSMs): Organizational Strategy Meetings are designed to improve engagement in practice change. These meetings will occur every 1-3 months and consist of a 3-4 member clinic leadership team, including providers and staff leaders. OSMs will be a chance for the study team to work with the clinic to identify organizational-level implementation strategies, share feedback, and discuss implementation barriers and strategies to overcome identified barriers.

Training: Study team members will conduct trainings (Table 1) by Zoom while the study is remote. All provider participants in the IMPACT project first will complete the pre-recorded online training modules. Then, there will be separate real-time trainings for therapists and prescribers (psychiatrists/nurse practitioners/primary care physicians). Trainings will be housed on the ETHOS Online Management System platform. See Table 1 for training outline.

The real-time motivational interviewing training is supplemented with an online avatar practice module.[39,40] The online avatar practice module includes a 15-minute didactic component where providers learn about motivational interviewing and techniques that can be used to guide clients with serious mental illness toward health changes and 15-minute practice conversations where providers take on the role of virtual provider avatar and practice the use of motivational interviewing techniques in simulated conversations about smoking cessation with consumer avatars on the Kognito platform. We will recommend that providers practice weekly for the first three months. An online dashboard will give providers an individualized report on their performance each time they practice.

Table 1. Training

Prescribers	**Therapists**
Online Training Modules (1 hr): Module 1: Why IMPACT? Module 2: Evidence-based treatment for smoking cessation for persons with SMI Module 3: Assessing Smoking Status Willingness to Quit Module 4: Pharmacotherapy for Smoking Cessation **Real-time Trainings (Zoom) (2 hrs):** Training 1 (1hr): Facilitating smoking cessation conversations Training 2 (1hr): Motivational Interviewing Approach to Pharmacotherapy **Online Motivational Interviewing Avatar (Recommended weekly 15-minute practice sessions for 3 months and then as needed/desired)**	**Online Training Modules (1hr):** Module 1: Why IMPACT? Module 2: Evidence-based treatment for smoking cessation for persons with SMI Module 3: Assessing Smoking Status Willingness to Quit Module 4: Pharmacotherapy for Smoking Cessation **Real-time Trainings (Zoom) (4 hrs):** Training 1 (2hrs): Facilitating Smoking Cessation Conversations and an Overview of Behavioral Counseling Training 2 (2hrs): Motivational Interviewing Approach to Smoking Cessation Behavioral Counseling **Online Motivational Interviewing Avatar (Recommended weekly 15-minute practice sessions for 3 months then as needed/desired)**

Data Collection:

Study data collection is outlined in Table 2 and in more detail below. Study team involvement in data collection is all virtual/remote.

Table 2. Study Data Collection	Who	Estimated Time	When
Qualitative Data Collection			
Provider Interviews	Select providers/clinic director (~6 per site)	30 minutes	Baseline, 12 months
Survey Measures			
Demographic Characteristics: age, sex, race, ethnicity, length of time at program, role in program, years at clinic, work hours, previous Motivational Interviewing training	All providers, clinic staff including leaders (~30 per site)	~5 minutes	Baseline
Implementation Climate: This is a measure of the degree to which an organization supports evidence-based practice implementation	All providers, clinic staff including leaders (~30 per site)	~3 minutes	Baseline
Acceptability, Appropriateness, and Feasibility of the Intervention Implementation Strategies: Measured with a brief 4-item practice instrument (AIM, IAM, FIM)[41]	All providers, clinic staff including leaders (~30 per site)	~5 minutes	Baseline, 12 months
Acceptability, Appropriateness, and Feasibility of the Evidence-Based Practice: Measured with a brief 4-item practice instrument (AIM, IAM, FIM)[41]	All providers, clinic staff including leaders (~30 per site)	~5 minutes	Baseline, 12 months
Clinic Social Network: A 4-question survey used to collect data about social networks	All providers, clinic staff including leaders (~30 per site)	~10 minutes	Baseline, 6, 12 months
Knowledge of Evidence-Based Smoking Cessation Treatment: A 16-item scale developed by our team to assess knowledge	All providers (~25 per site)	~10 minutes	Baseline, 12 months
Self-Efficacy to deliver evidence-based smoking cessation treatment	All providers (~25 per site)	~5 minutes	Baseline, 12 months
Motivation Measures: Degree to which providers agree or disagree with statements that deal with aspects of the intervention to improve use of evidence-based smoking cessation treatment.	All providers (~25 per site)	~3 minutes	Baseline, 12 months
Beliefs about Motivational Interviewing Questionnaire	All providers (~25 per site)	~2 minutes	Baseline, 3, 6, 12 months
Importance and Confidence of Using Motivational Interviewing	All providers (~25 per site)	~2 minutes	Baseline, 3, 6, 12 months
Perceived Usefulness of Motivational Interviewing Avatar	All providers (~25 per site)	~2 minutes	12 months
Fidelity Measures			
Avatar Motivational Interviewing Performance Measurements: from use of motivational interviewing techniques in simulated online conversations	All providers (~25 per site)	Recommended weekly 15-min practice sessions	Baseline, 3, 6, 12 months
Fidelity to Motivational Interviewing: Standardized Actor Interviews will be conducted to assess fidelity to motivational interviewing. **Fidelity to behavioral smoking cessation counseling:** Standardized Actor Interviews will be conducted to assess fidelity to smoking cessation behavioral counseling sessions	All providers (~25 per site)	30 minutes	3, 6, 12 months
Smoking and Smoking-Cessation Measures			
These are our primary measures of fidelity to evidence-based smoking cessation treatment. **Guideline-concordant smoking cessation treatment:** *Measures will be calculated at site & provider levels* **Smoking status assessment rates:** % of visits where smoking status assessment is documented. **Willingness-to-quit assessment rates:** % of visits where willingness-to-quit assessment is documented. **Prescription Rates:** % of willing-to-quit smokers prescribed, or offered but refused, cessation pharmacotherapy.[2] **Behavioral Counseling Rates:** (1) % of not willing-to-quit	All mental health consumers (patients) (~3000 per site)		Baseline through 12 months

smokers given brief behavioral counseling to increase willingness-to-quit; and (2) % of willing-to-quit smokers who were referred to the clinic's cessation counselor.[2] Among willing-to-quit smokers referred the counselor, we will also measure the number of counseling sessions completed.			
7-day abstinence: % of willing-to-quit consumers abstinent for ≥7 days self-report, documented in the EMR	All mental health consumers (patients) (~3000per site)		Baseline through 12 months
Other Patient Measures Year of birth, gender, race/ethnicity, primary mental health diagnosis, hospitalization during the study period	All mental health consumers (patients) (~3000 per site)		Baseline through 12 months

Qualitative Data Collection

Provider Interviews: Study team members will conduct up to 40 (8 per site) 30-minute interviews with the clinic director and approximately 7 other providers at each site at baseline and 12 months. Interviews will elicit providers' perceptions of: barriers to smoking cessation treatment and implementation strategies to overcome barriers. Interviews will obtain information on how the 5 work system elements (people, tasks, tools and technologies, environment and organization) influence delivery of evidence-based smoking cessation treatment for consumers with SMI. Semi-structured interviews will be conducted using a standard protocol for both pre-implementation (baseline) and post-implementation (12 months). Interviews will be audio-recorded, and recordings will be transcribed using Production Transcripts, Inc.

Surveys

Surveys will be administered via email with instructions and a link to the surveys in REDCap. Surveys may also be delivered in hard copy if needed and mailed back to the study team. We will recruit and survey the staff/providers at the 4 community mental health clinic study sites.

Demographic Characteristics: Will include age, sex, race, ethnicity. We will also ask about their current role in the at the clinic, years worked at the clinic, work hours, and any prior Motivational Interviewing training. This survey is 11 questions.

Implementation Climate: Ehrhart's implementation climate scale;[42] overall score of 4 = excellent implementation climate. This is a measure of the degree to which an organization supports evidence-based practice implementation.

Acceptability, Appropriateness, and Feasibility of the Intervention Implementation Strategies: Acceptability, feasibility and appropriateness of the intervention implementation strategies (IMPACT smoking cessation program, trainings, avatar, resource manuals, organizational strategy meetings, coaching) will be measured with validated 4-item measures.[41]

Acceptability, Appropriateness, and Feasibility of the Evidence-Based Practices: Acceptability, feasibility and appropriateness of the evidence-based practices (smoking status and willingness-to-quit assessment, pharmacotherapy, behavioral counseling, brief motivational enhancement counseling will be measured with validated 4-item measures.[41]

Clinic Social Network: This is a 4-question survey used to provide information about how people interact in each clinic. The survey will include a staff list in order to identify co-workers that regularly interact. Once data has been collected, names from the staff list will be deleted.

Knowledge of Evidence-Based Smoking Cessation Treatment: This is a 16-item scale developed by our team to assess knowledge of evidence-based smoking cessation treatment (e.g. that most people with SMI want to quit and that varenicline is safe and effective for people with SMI).

Self-Efficacy: Assessing self-efficacy to deliver evidence-based smoking cessation treatment measured as a numeric score created by averaging 10 items adapted from Compeau & Higgins' task-focused self-efficacy scale[43] (score>8 = high self-efficacy).

Motivation Measures: Measured by assessing the degree to which providers agree or disagree with each statement, and the degree to which providers find each item important or not important. Statements deal with aspects of the IMPACT intervention to improve use of evidence-based smoking cessation treatment.

Beliefs about Motivational Interviewing Questionnaire: A 7-question survey assessing the extent to which each person agrees with statements about motivational interviewing.

Importance and Confidence of Using Motivational Interviewing: A 6-question survey assessing the importance and confidence each person has with motivational interviewing.

Perceived Usefulness of Motivational Interviewing Avatar: A 6-item survey assessing the impact of the avatar on each person's use of motivational interviewing and performance in the study.

Fidelity Measures

Avatar Motivational Interviewing Performance Measurements: Providers will conduct 15-minute practice conversations where they practice use of motivational interviewing techniques in simulated conversations about tobacco smoking cessation with patient avatars. An online dashboard will give providers an individualized report on their performance each time they practice.

Fidelity to Motivational Interviewing: Standardized Actor Interviews: Providers will conduct 30-minute audio-recorded phone interviews with standardized patient actors. These standardized patient actors are trained actors playing roles of patients with SMI who smoke. Used to assess fidelity to motivational interviewing.

Fidelity to behavioral smoking cessation counseling: Standardized Actor Interviews: Providers will conduct 30-minute audio-recorded phone interviews with standardized patient actors**.** These standardized patient actors are trained actors playing consumers with SMI who smoke. Used to assess fidelity to smoking cessation behavioral counseling sessions.

Smoking and Smoking Cessation Processes of Care, Patient Measures

Providers will document smoking-related processes of care during the study (see IMPACT Study Medical Record Variables document). We will work with each community mental health clinic on how providers will do this. At Johns Hopkins, this information will be entered into EPIC using smart forms and adapting current clinic note templates. For other study clinic sites, data will come from a combination of electronic health records and from REDCaP surveys that clinic provider participants complete when they assess smoking status or provide smoking cessation treatment. If the other sites are not able to change their electronic health records to collect smoking cessation processes of care or provide documentation of smoking cessation processes of care directly to us, we plan to use REDCaP to supplement available electronic health record data. We describe in more detail below in the data management section.

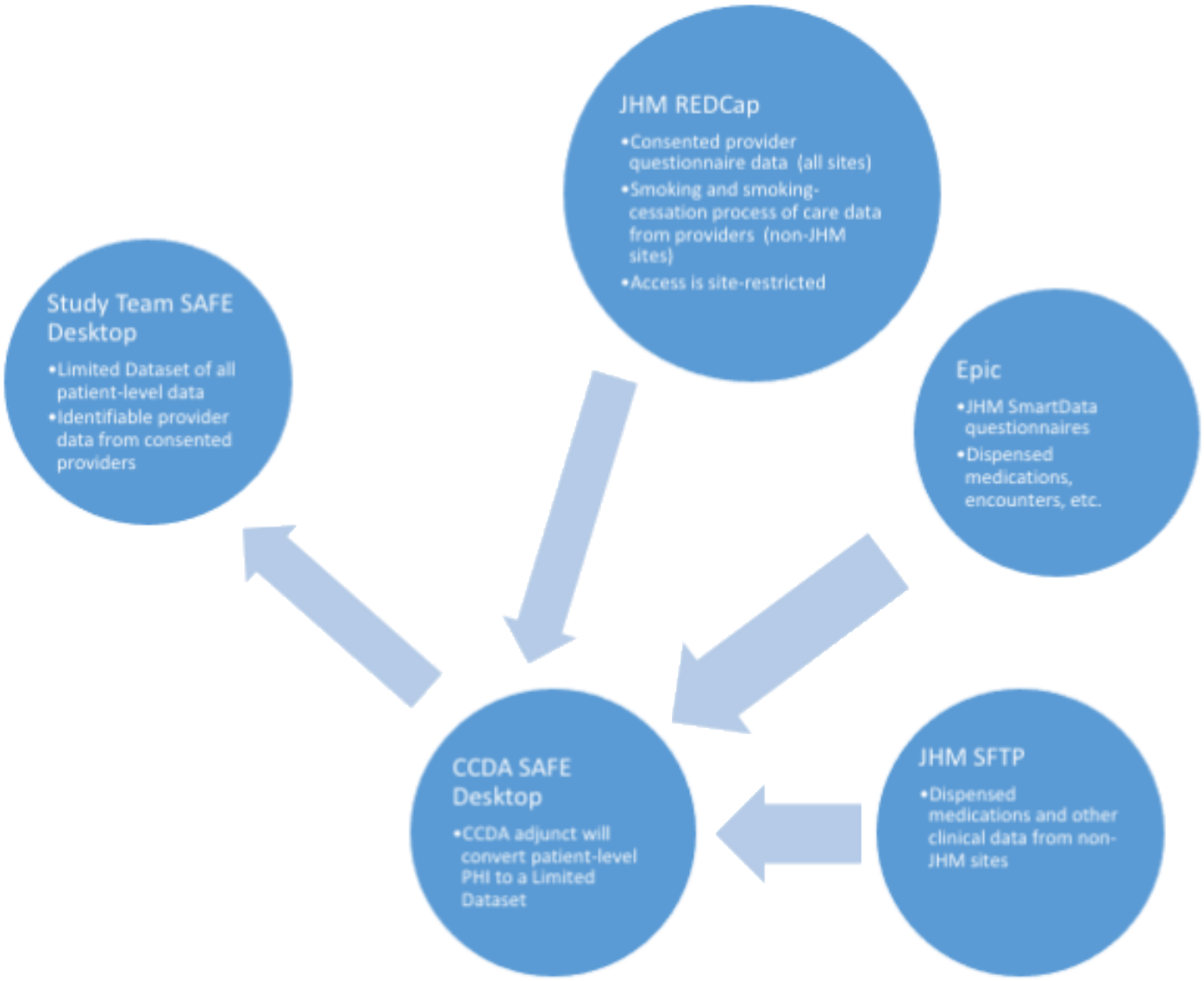
Data Management:

Qualitative data. Interview data will be audio or video-recorded and recordings will be transcribed using Production Transcripts, Inc or another approved Johns Hopkins vendor. Names will be removed from transcripts. Recordings will be stored in a Johns Hopkins secure network drive and will be destroyed when analyses are complete. Standardized actor interview recordings will be reviewed by experts in motivational interviewing and smoking cessation behavioral counseling to assess for fidelity to motivational interviewing

practices and fidelity to IMPACT smoking cessation behavioral counseling sessions. These recordings will be stored in a Johns Hopkins secure network drive or OneDrive.

Quantitative data. Each participant will be assigned a unique study ID number for data collection. Study team members are trained to protect integrity and confidentiality of the data. Staff and provider questionnaire data will be stored in a Johns Hopkins REDCap database. Kognito, a health simulation company, developed the avatar simulations for this project and hosts the avatar training platform and dashboard. Avatar performance measurement data for motivational interviewing practice conversations is accessible only by the individual study participant (provider) and the study team, not shared outside Kognito. Kognito stores data securely behind two firewalls.

Figure. Data sources, management and security.



This figure describes planned data management and security for this study. We developed this plan with Bonnie Woods, IT Director for the Johns Hopkins ICTR. The ICTR/CCDA will serve as an honest broker both for data coming from Johns Hopkins and from non-Johns Hopkins clinic sites. They will create limited datasets for

patient data for study team use on a study team SAFE Desktop including linking REDCap process of care data from to the appropriate patient. REDCap: We will store questionnaire data from staff/providers who agree to participate in the study in a Johns Hopkins REDCap database, restricted by study site. REDCap will also be used if needed for providers at non-Johns Hopkins study sites to document processes of care information for smoking cessation treatment to supplement data from electronic health records. One site (Vesta) plans to use a spreadsheet to document deidentified process of care data to be placed on a Johns Hopkins OneDrive. EPIC: Johns Hopkins EPIC data from smartforms developed for this project and from clinic notes will be used for process of care information at the Johns Hopkins site. Additional data from EPIC will be used including for demographics, medications, and information about number of outpatient encounters. (see IMPACT Study Medical Record Variables document). Weekly reports of process of care data will be provided to the study team, not identifying patients. SFTP: Electronic medical record data from non-Johns Hopkins study sites will be transmitted to Johns Hopkins through SFTP. The ICTR/CCDA will serve as an honest broker and store data on a CCDA Safe Desktop while preparing the limited datasets for the study team.

c. Blinding, including justification for blinding or not blinding the trial, if applicable.
Not applicable

Justification of why participants will not receive routine care or will have current therapy stopped.
Not applicable

d. Justification for inclusion of a placebo or non-treatment group
Not applicable

e. Definition of treatment failure or participant removal criteria.
Not applicable

f. Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely.
Not applicable

5. Inclusion/Exclusion Criteria

Community mental health clinic staff (e.g., licensed counselor, psychologist, social worker, nurse practitioner, physician, organizational leader, clinic director, administrative assistant) at one of the 4 community mental health clinic study sites. All are 18 years and older and English-speaking.

Clinic patients are by definition persons with serious mental illness seeking treatment at community mental health outpatient clinics. All are 18 years and older.

6. Drugs/ Substances/ Devices – Not applicable

a. The rationale for choosing the drug and dose or for choosing the device to be used.
b. Justification and safety information if FDA approved drugs will be administered for non-FDA approved indications or if doses or routes of administration or participant populations are changed.
c. Justification and safety information if non-FDA approved drugs without an IND will be administered.

7. Study Statistics

a. Primary outcome variable and analytic plans.

We will conduct three main analyses. First, we will assess the effects of the implementation intervention (baseline and 12 months) on providers' knowledge and self-efficacy, the mechanisms through which the

implementation intervention is designed to improve delivery of evidence-based smoking cessation treatment, using a generalized linear mixed effects modeling approach. The mean model will include a binary pre/post indicator, fixed effects for the four study sites, and provider demographic characteristics. Second, we will evaluate the effects of the implementation intervention (baseline and 12 months) on consumer level guideline-concordant care and 7-day smoking abstinence outcomes using a multi-level modeling approach. Third, we will assess mediators and moderators. Specifically, we will test whether providers' knowledge and self-efficacy mediated the implementation intervention's effects on consumer outcomes by estimating the magnitude of attenuation on intervention effects in the multi-level models of consumer outcomes with versus without these potential mediators. We will also assess the potential moderating effects of implementation climate by adding appropriate interaction terms to main models. We will use descriptive statistics to analyze survey measures of staff perceptions of the acceptability, feasibility and appropriates of the implementation intervention strategies and the IMPACT evidence-based practices. Interview transcripts will be analyzed in NVivo V.11, using inductive coding to identify key themes. Survey analysis will be done using Stata 14 or SAS software.

To analyze the standardized actor interviews, we will use the Motivational Interviewing Treatment Integrity (MITI) rating system and our IMPACT Smoking Cessation Counseling Session skills Assessment Form. For MITI: We will MITI code random 30-minute segments of audio-recorded interactions with standardized patient actors. Standardized consumer scenarios will be scripted to reflect the kind of situations community mental health clinicians would likely encounter with clients; this method has predictive validity in terms of providers' performance with real patients.[44] "Global" scores provide benchmarks of "fair" or "good" on the technical (e.g. capacity to elicit motivations for change) and relational (person-centered) aspects of motivational interviewing. "Behavior Counts" are tallies of 10 specific clinician behaviors, e.g. giving information and "persuading with permission." Summary measures indicate the degree to which clinicians are motivational interviewing adherent (e.g. affirm, emphasize autonomy, seek collaboration), motivational interviewing non-adherent (e.g., confront, persuade), and show an appropriate ratio of questions to reflections. For fidelity to evidence-based smoking cessation treatment: all interviews will be scored by our team to assess individual clinician's skills implementing the intervention.

b. Secondary outcome variables. N/A
c. Statistical plan including sample size justification and interim data analysis. N/A
d. Early stopping rules. N/A

8. Risks

Risk of loss of confidentiality and negative implications for employment are the main risks. We expect these risks to be extremely low. Plans to minimize this risk are described below.

a. Medical risks, listing all procedures, their major and minor risks and expected frequency.

For the implementation intervention, community mental health clinic providers (including primary care providers) are already providing care including some smoking cessation treatment for their patients with serious mental illness. For this project, we will work with community mental health clinic providers to implement evidence-based best tobacco smoking cessation practices. The evidence-based practices in this project are based on current guidelines and are within the clinicians'current scope of practice. Thus, we do not expect there to be an increased risk for clinic patients.

Community mental health clinic providers and staff may become tired or bored during surveys or interviews.

b. Steps taken to minimize the risks.

Community mental health clinic leaders, providers and staff will be appropriately recruited and informed of the study by the study team with waiver of documentation of informed consent. The study team will inform them

that they do not have to answer any questions they do not want to, and that their employment or evaluations will not be affected by their responses.

c. Plan for reporting unanticipated problems or study deviations.

Dr. Daumit, internist with experience in working with persons with SMI and staff in community mental health settings, will be responsible for data safety and monitoring. If new guidelines for smoking cessation treatment were to be released during the study period, we will make any appropriate modifications in protocols (resource guides, manuals), during coaching sessions and expert consultation, and communicate with the study sites. If safety issues about management of smoking cessation treatment in individual clients arise, Dr. Daumit will communicate with the provider or clinic director as appropriate. Any unanticipated problems will also be reported to the IRB. We expect any issues to be rare.

d. Legal risks such as the risks that would be associated with breach of confidentiality.

Risk of loss of confidentiality is the main risk. We expect this risk to be extremely low, as we will be taking multiple safeguards to protect the data. To protect against breach of confidentiality, all information will be considered confidential. This confidentiality will be assured through several mechanisms.

As per above, community mental health providers, primary care providers and staff will be appropriately recruited and informed of the study by the study team with waiver of documentation of informed consent. The study team will inform them that they do not have to answer any questions they do not want to, and that their employment or evaluations will not be affected by their responses. Data will not be presented in such a way that identity can be inferred. As described in Data Management, data will be stored in Johns Hopkins secure drives. Folders and spreadsheets will have password protection. For qualitative data, each interviewee will be assigned a study identifier. The link to the study ID will be held in a locked file. Interview transcripts will have names (if mentioned during interview) removed, and no participants will be identified by name in any publications. For quantitative data, each staff participant will be assigned a unique study ID number for data collection and data will be stored in REDCap. The study team will receive limited datasets for patient data on SAFE Desktop.

e. Financial risks to the participants. N/A

9. Benefits

a. Description of the probable benefits for the participant and for society.

There is no benefit to individual participants. This research will help stakeholders have a greater understanding of the organizational and provider-level barriers to delivery of evidence-based smoking cessation treatment in community mental health settings. This research will also inform development of the implementation intervention tested in this R34.

10. Payment and Remuneration

a. Detail compensation for participants including possible total compensation, proposed bonus, and any proposed reductions or penalties for not completing the protocol.

Study participants will be paid $50 for completing each interview. Providers will be paid $25 for each standardized actor interview. All study participants will be compensated $20 for completion of surveys administered at baseline data collection and 12 month data collection and $10 for completion of surveys at 3 and 6 months. Providers will receive $50 for documenting smoking related processes of care during the study.

11. Costs

a. Detail costs of study procedure(s) or drug (s) or substance(s) to participants and identify who will pay for them.

There are no costs to participants.

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