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# Assessing barriers to providing tobacco use disorder treatment in community mental health settings with a revised version of the Smoking Knowledge, Attitudes, and Practices (S-KAP) instrument



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# ABSTRACT

*Background*: Tobacco use disorder (TUD) rates are 2–3 times higher among people with serious mental illness (SMI) than the general population. Clinicians working in outpatient community mental health clinics are well positioned to provide TUD treatment to this group, but rates of treatment provision are very low. Understanding factors associated with the provision of TUD treatment by mental health clinicians is a priority.

*Methods*: This study used baseline data from an ongoing cluster-randomized clinical trial evaluating two approaches to training clinicians to increase TUD treatment. Following a psychometric assessment of our assessment tool, the Smoking Knowledge, Attitudes, and Practices (S-KAP) instrument, a new factor structure was evaluated utilizing confirmatory factor analysis. Structural equation modeling was then used to examine the associations between TUD treatment practices and clinician, setting, and patient characteristics in a sample of 182 mental health clinicians across 10 mental health clinics.

*Results:* Clinician but not setting or patient characteristics emerged as significant correlates of providing TUD treatment. Specifically, clinicians' general ethical commitment to providing TUD services and perceptions of their skills in providing this type of care were associated with providing TUD treatment. In contrast, clinician perceptions of patient motivation, anticipated quit rates, or available setting resources were not significantly associated with providing TUD treatment.

*Conclusions*: Enhancing community mental health clinician TUD treatment skills and commitment to providing such services may reduce TUD rates among people with SMI. Future studies should evaluate interventions that target these factors.

# 1. Introduction

Tobacco use disorder (TUD) rates among those with SMI are 2–3 times higher than in the general population (Prochaska, Das, & Young-Wolff, 2017). Consequently, individuals with SMI experience disproportionately higher rates of tobacco-related health consequences, including early mortality (Miller, 2006; Tam, Warner, & Meza, 2016).

Thus, developing effective methods to address tobacco use among those with SMI is a priority for the field of tobacco control, as highlighted by the National Cancer Institute (Tobacco Control Research, 2016)

Health care clinicians can play an important role in reducing TUD rates by assessing tobacco use and providing evidence-based treatment (Stead et al., 2013; Papadakis et al., 2010). In general, however, clinicians do not consistently adhere to this practice guideline (Babb,

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https://doi.org/10.1016/j.addbeh.2020.106735 Received 11 June 2020; Accepted 9 November 2020 Available online 19 November 2020 0306-4603/© 2020 Elsevier Ltd. All rights reserved. Malarcher, Schauer, Asman, & Jamal, 2017), with one study documenting that interventions were offered to only 34% of patients with TUD (Silfen, Cha, Wang, Land, & Shih, 2015). The evidence further suggests that mental health clinicians are even less likely to adhere to this practice guideline, with reports estimating that as few as 9–12% of patients with TUD receive treatment (Himelhoch & Daumit, 2003; Montoya, Herbeck, Svikis, & Pincus, 2005). Most concerning, mental health clinicians' rates of addressing tobacco use appear be declining over time (Rogers & Sherman, 2014).

Poor rates of TUD screening and treatment at mental health clinics may reflect organizational barriers more than clinician characteristics (Morris, Waxmonsky, May, & Giese, 2009; Prochaska, 2010). For example, nearly 50% of US psychiatric facilities permit patient smoking on premises (Marynak et al., 2018) and most mental health agencies do not require or provide TUD treatment training (Rojewski et al., 2019). Limited training may also help explain why 20% of mental health clinicians believe that quitting tobacco use during mental health treatment can undermine recovery (Flitter et al., 2018) by contributing to poorer mental health including self-injurious behavior and increased use of alcohol or other substances (Morris et al., 2009; Prochaska, 2010; Himelhoch, Riddle, & Goldman, 2014). In order improve TUD screening and treatment rates within mental health settings for the benefit of people with SMI, it may be necessary to draw on novel frameworks that adopt a systems-level perspective regarding the provision of TUD treatment (e.g., Addressing Tobacco Through Organizational Change; Ziedonis et al., 2007). A better understanding of systems-level barriers can help inform the implementation of organizational interventions designed to improve the quality of care. Toward that end, the primary objective of this cross-sectional study of baseline data from a larger trial was to identify barriers to the provision of TUD treatment by clinicians working within outpatient community mental health agencies.

# 2. Methods

Baseline data were collected from participants (clinical staff from mental health agencies) who were partaking in an ongoing clusterrandomized clinical trial. The trial is designed to evaluate two different approaches to training clinicians at their outpatient mental health agency with the goal of increasing TUD treatment in the context community mental health care (ClinicalTrials.gov of ID: NCT02849652). Community mental health clinics (CMHCs) within Philadelphia's CBH system (N = 10) have been randomized to one of the two interventions (training alone vs. training and organizational change technical assistance). Sites were eligible for this trial if they had an electronic health record, provided access to prescription data (tobacco use treatments), and could enroll at least 12 staff members to the clinical trial. Twelve sites were approached to join the study, of which 10 enrolled and 2 declined. For a complete description of the study procedures see Flitter, Lubitz, and Ziedonis (2019).

# 2.1. Participants

To be eligible for enrollment, participants had to be at least age 18; have clinical, administrative, or supervisory duties within the agency, be English proficient, and be able to provide informed consent. A total 182 personnel were recruited from 10 sites, ranging from 12 to 25 participants per site.

# 2.2. Procedures

The Institutional Review Boards at the University of Pennsylvania and the City of Philadelphia provided approval for the trial. Following randomization at the level of the CMHC, research personnel attended clinics to enroll staff prior to the intervention. Interested, eligible staff provided informed consent and completed a baseline self-report assessment.

#### 2.3. Measures

# 2.3.1. Demographic, smoking, and employment characteristics

Demographic (age, gender, race, education) and employment characteristics (type of position, years of experience, average hours/week of clinic work, average number of clients) were collected for all staff. In addition, personnel were asked to describe the TUD treatment resources and practices available at their site and whether a system was used to identify smokers.

# 2.3.2. Staff smoking knowledge, attitudes, and practices instrument (S-KAP)

The S-KAP (Delucchi, Tajima, & Guydish, 2009) is composed of 44 self-report Likert-type items that form five subscales: staff knowledge of the health risks of smoking (Knowledge), perceived barriers to offering TUD treatment services (Barriers), beliefs and attitudes regarding the importance and best methods for providing services (Beliefs & Attitudes), perceived self-efficacy in delivering services (Self-Efficacy), and frequency of delivering specific TUD treatment practices (Practices). The S-KAP was developed with staff working in substance use and HIV care settings; therefore, minor changes were made to adapt the instrument for this study (e.g., changing references to "using drugs" to the more general "psychiatric illness"). In addition, one question regarding knowledge about the links between HIV and the risk of developing smoking-related illness was eliminated.

# 2.4. Analyses

Descriptive statistics summarized sample demographic, smoking, and employment characteristics; the frequency of delivering TUD treatment practices (S-KAP Practices subscale) was also assessed. The primary analyses focused on whether a set of predictors (i.e., S-KAP subscales) were related to delivering TUD treatment practices as measured by the S-KAP Practices subscale. As a preliminary step, we assessed the psychometric properties of the S-KAP subscales in the current sample by examining Cronbach's alpha coefficients and replicating the principal factor analysis conducted by Delucchi et al. (2009). The results of these analyses (see below) suggested that not all the S-KAP subscales were reliable in this sample. Thus, a new factor structure was evaluated utilizing confirmatory factor analysis (CFA) and structural equation modeling (SEM) with Mplus v8.3 (Muthén & Muthén, 1998-2017) on the S-KAP items to evaluate the fit of the data to a new model. Each latent variable was built and evaluated using maximum likelihood methods. Modification indices that identified alternations that would both significantly improve model fit and were consistent with the objectives of this study were considered. A final model was evaluated using SEM to determine whether the Practices latent variable could be predicted from the newly specified latent variables developed in the present study.

# 3. Results

# 3.1. Sample characteristics and TUD treatment practices

Descriptive information for the sample is provided in Table 1. The majority of the staff were female, came from racial minority groups, and completed more than a high school education. Most staff reported working full-time hours, with the majority of their time spent in direct patient contact. Regarding TUD treatment practices, a significant majority of participants reported that their organization did not routinely ask about tobacco use or offer TUD treatment.

# 3.2. Correlates of TUD treatment practices: exploratory analyses

When the S-KAP subscales were calculated based on Delucchi et al. (2009), Cronbach's alpha coefficients for the Practices, Knowledge, and

#### Table 1

Sample Characteristics and TUD Practices.

Characteristics ( $N = 182$ )	% or Mean (SD)				
Age, years	41.2 (11.8)				
Gender (% female)	75.1				
Race (% Nonwhite)	65.2				
Smoking status (% smoking)	24.3				
Education (% $\leq$ high school)	4.4				
Years at agency	5.2 (5.8)				
Hours/week	38.0 (10.1)				
Patient hours/week	22.8 (14.1)				
Primary Role:					
Clinical/Counseling	40.9				
Case Management	22.1				
Administrative	17.7				
Other	19.3				
TUD treatment offered? <sup>1</sup>					
Offered at clinic	28				
Not offered at clinic	39				
Unsure if offered at clinic	33				
Types of treatment offered:					
Information/pamphlets	19				
NRT	20				
NRT + other FDA-approved pharmacotherapy	4				
Counseling	13				
Referrals	3				
How often clients asked about tobacco use?					
Frequently (i.e., often, very often, or routinely)	38				
How often clients advised to quit smoking?					
Frequently (i.e., often, very often, or routinely)	40				

<sup>1</sup> This represents the percentage of staff who reported whether TUD treatment was offered, not necessarily the percentage of clinics that offered TUD treatment.

Barriers subscales were 0.89, 0.87, and 0.79, respectively. However, despite what appeared to be acceptable inter-item reliabilities, it has been well-recognized that coefficient alpha is not a measure of scale unidimensionality (Dunn, Baguley, & Brunsden, 2014). Moreover, the alpha coefficients for Beliefs & Attitudes and Self-Efficacy subscales were 0.21 and 0.68, respectively. Exploratory factor analyses supported a five-factor solution, but multiple items from the Barriers, Beliefs & Attitudes, and Self-Efficacy scales did not load (<0.30) on their originally assigned subscale factors. Thus, we assessed for a new factor structure using CFA. For the factors that had good reliability and factor loadings (Practices and Knowledge), latent variables were constructed according to the original scoring guidelines with minor modifications. For the factors with poor reliability and/or factor loadings, exploratory analyses informed the specification of new latent variables.

# 3.2.1. Practices

The exploratory results for the Practices scale suggested good reliability overall but at least two items from the scale loaded less well (i.e., <0.50 standardized loadings) than the other items ("In the past month, how frequently did you encourage your patients who smoke to not smoke in the presence of infants or children?" and "Smoking cessation counseling is an important part of my job."). A CFA model was specified first including all of the items from this scale, next with these two items removed to evaluate improvement of fit, followed by other modifications as indicated. The first model had poor fit,  $\chi^2(27) = 82.91$ , p < .001, CFI = 0.934, RMSEA = 0.107. Removing the two items improved the fit,  $\chi^2(14) = 40.81, p < .001, CFI = 0.964, RMSEA = 0.103, but still did not$ achieve acceptable fit. A third model was tested utilizing only the first four items, representing the comprehensive "4 A's" of TUD treatment: "Ask, Advise, Assist, Arrange" (Manley, Epps, & Glynn, 1992). The remaining 3 items that were dropped represented idiosyncratic TUD interventions (e.g., "In the past month, how frequently did you encourage your patients who smoke to reduce smoking to 5 or fewer cigarettes/day, if patient stated they could not quit"). This model achieved a good fit,  $\chi^2(2) = 2.70$ , p = .259, CFI = 0.998, RMSEA = 0.044, with all items loading well. This latent variable, Practices, served as the measure of TUD practices for subsequent analyses.

# 3.2.2. Knowledge

The exploratory results for Knowledge suggested good reliability overall with all items loading well (i.e., >0.50 standardized loadings). A CFA was specified including all of the items, which produced a poor fit,  $\chi^2(14) = 108.43, p < .001, CFI = 0.859, RMSEA = 0.193.$  Items that assessed general knowledge of smoking hazards (e.g., "The hazards of smoking have been clearly demonstrated") loaded less well (<0.50), whereas items that assessed more specific knowledge (e.g., "Smoking increases the risk of diabetic ulcers") loaded more strongly. Furthermore, modification indices indicated that correlating general items and specific items, respectively, would improve fit and suggested a possible two-factor structure reflecting general and specific types of knowledge. A two-factor model was evaluated (Knowledge: general, Knowledge: specific), which improved fit but not sufficiently ( $\chi^2(3) = 47.51$ ,  $p < 10^{-10}$ .001, CFI = 0.949, RMSEA = 0.121). One additional change was made to cross-load a single item that represented general and specific knowledge ("Smoking increases the risk of heart attack") on both factors. This twofactor model achieved good fit,  $\chi^2(12) = 15.31$ , p = .225, CFI = 0.995, TLI = 0.991, RMSEA = 0.039, and was used in subsequent analyses.

# 3.2.3. Barriers, beliefs & attitudes, and self-efficacy

Exploratory results suggested adequate reliability for the Barriers subscale, albeit less robustly vs. the Practices and Knowledge scales. Three of the 11 items loaded <0.50, which included an item on patient interest in TUD treatment, another on whether other health problems required attention, and a third tapping whether participants felt capable of tailoring cessation counseling to patient needs. The items that composed the Barriers subscale potentially represent multiple dimensions of barriers, including patient (interest, motivation), setting (availability of recourses), and clinician (training) barriers that may not reflect a single latent variable. As a first step, a model that specified all items loading on a single factor resulted in a very poor fit,  $\chi^2(44) = 278.91$ , p < .001, CFI = 0.643, RMSEA = 0.172. Item loadings mirrored the exploratory results and removing the same items that did not load in either analysis did not result in a better fit,  $\chi^2(35) = 260.63$ , p < .001, CFI = 0.652, RMSEA = 0.189.

The modification indices did not identify a way to structure the Barriers, Beliefs & Attitudes, and Self-Efficacy subscales to achieve a good fit but instead provided evidence that the scale items represented multiple factors. On its face, Beliefs & Attitudes items assess general beliefs about the impact of smoking cessation on mental health, the clinical ethics of addressing smoking cessation, and clinical tactics regarding the most opportune time to address smoking cessation during mental health treatment. Similarly, the Self-Efficacy scale appeared to assess multiple dimensions, including clinician confidence in their ability to help patients quit smoking, beliefs about expected patient smoking cessation success rates if services were offered, and how much emphasis should be placed on TUD treatment in general.

# 3.2.4. New subscales

The pooled set of items from the Barriers, Beliefs & Attitudes, and Self-Efficacy subscales were initially grouped into patient, setting, and clinician characteristics. The patient items were further specified as: *patient: motivation*, to assess participant perceptions of patient interest in quitting, and *patient: expected outcomes*, to assess participant perceptions of the quit rates patients would achieve if treatment were offered. The setting items were fit as one latent variable, *setting: resources*, which assessed participant perceptions of available TUD treatment resources (e.g., patient education materials, access to community referrals, having sufficient time to provide treatment). The clinician items were specified to be indicators of three latent variables: *clinician: tactics*, to assess participant beliefs about how and when to best deliver TUD treatment services, *clinician: skills*, to assess participant perceptions about their level of training and competence in providing treatment, and *clinician*: *ethics*, to assess participant beliefs about whether TUD treatment should be a priority and focus of care independent of available resources, training level, or anticipated patient outcomes. This model resulted in poor fit to the data ( $\chi^2(362) = 1032.76$ , p < .001, CFI = 0.497, RMSEA = 0.101). Model revisions were made through an iterative process, guided by modification indices. These revisions entailed reassigning individual items from one latent variable to another (e.g., moving 'smoking cessation counseling is an important part of my agency's mission' from *setting: resources* to *clinician: ethics*), allowing an item to cross-load, removing items that did not appear to load on any latent

variable (3 instances), or fixing correlations between specific latent variables to 0 (5 instances). Note: latent variables are typically allowed to correlate in SEM but in this model, where latent variables did not correlate and theoretically would be expected to be orthogonal (e.g., *patient: motivation* and *clinician: skills*), these paths were fixed to 0 for parsimony. The final model had an acceptable fit to the data,  $\chi^2(281) = 443.516$ , p < .001, CFI = 0.864, RMSEA = 0.056, with each item significantly loading on its latent variable. The item loadings for the final set of latent variables, including *practices* and *knowledge*, are shown in Table 2.

# Table 2

Standardized Factor Loadings	from the Confirmatory	Factor Analysis ( $N = 182$ ).
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Factor Grouping/Item Content	Original S-KAP Subscale	1	2	3	4	5	6	7	8	9
Practice [1]										
Ask patients whether they smoked	Р	0.626								
Advise patients who did smoke to quit smoking	Р	0.851								
Assist patients with referrals/advice	Р	0.801								
Arrange follow up visit to discuss quitting smoking	Р	0.728								
Know [2]										
Hazards of smoking clearly demonstrated	K		0.767							
Hazards of second-hand smoke demonstrated	K		0.843							
Smoking increases the risk of heart attack*	K		0.370							
Know 2 [3]										
Smoking increases the risk of heart attack*	K			0.434						
Smoking increases the risk of diabetic ulcers	K			0.831						
Smoking increases the risk of impotence	K			0.883						
Smoking increases the risk of bladder cancer	K			0.844						
Smoking increases risk of poor wound healing	K			0.761						
Patient Motivation [4]										
Patients not interested	В				0.544					
Patients do not comply	В				1.137					
Patient: Expected Outcomes [5]										
Counseling by a clinician helps motivate smokers to quit	B&A					0.378				
If counseled, percent would try to quit smoking > 6mo	SE					0.439				
If counseled, percent successfully quit > 6mo	SE					0.330				
My patients follow my advice about behavior change	SE					0.596				
My patients are concerned about smoking	SE					0.575				
My patients who smoke want to quit	SE					0.684				
Setting: Resources [6]										
Lack of time	В						0.636			
Lack of reimbursement	В						0.708			
Lack of community resources to refer patients	В						0.588			
Lack of patient education materials	В						0.475			
Other health problems require attention	В						0.488			
Lack of training	В						0.470			
Clinician: Tactics [7]										
Complexity of smoking cessation guidelines	В							0.636		
If a patient has been in recovery for < 6mo quitting would threaten	SE							0.230		
recovery										
For clients who use drugs and smoke cigarettes, which should come first	SE							-0.195		
Clinician: Skills [8]										
Lack of training	В								0.144	
Tailor cessation counseling	В								-0.729	
Have the required skills	SE								-0.604	
Ability to treat nicotine dependence	SE								-0.401	
I know where to refer	SE								-0.505	
Clinician: Ethics [9]										
Clinicians should advise patients to quit, even if it's not the reason for visit	B&A									0.696
Clinicians should make appointments specifically to help patients quit	B&A									0.524
How much emphasis do you believe should be placed on nicotine dependence treatment for your patients?	SE									0.410
Cessation counseling is an important part of my agency	B&A									0.494
What is the best point to encourage clients to stop smoking	B&A									0.529

Note. The original Smoking Knowledge, Attitudes, and Practices (S-KAP) Instrument subscales include Practices (P), Knowledge (K), Barriers (B), Beliefs and Attitudes (B&A), and Self-Efficacy (SE). Items with an \* were cross-loaded on two latent variables.

# 3.3. Prediction models of TUD treatment practices

SEM was used to build a prediction model that specified the Practices latent variable as the outcome and the remaining latent variables developed above as predictors. Covariates included whether the clinics reported use of a system to identify patients who use tobacco and the clinician's tobacco use status. The first model that included all the predictors failed to converge. Therefore, an iterative process was used to test one predictor at a time. An updated model was specified that included only the significant predictors: clinician: skills, clinician: ethics, and the item that assessed whether a system was used to identify patients who smoke. This model achieved an acceptable fit,  $\chi^2(86) =$ 124.99, *p* = .004, CFI = 0.937, RMSEA = 0.050 (Fig. 1). Finally, given the multilevel structure of the data (i.e., staff participants nested within clinics) and yet a small number of clusters (i.e., 10 clinics), a final model was specified using type = complex analysis option in Mplus (McNeish, Stapleton, & Silverman, 2017). This approach did not change the pattern of results or statistical significance of effects.

## 4. Discussion

The present study sought to identify factors that are associated with the provision of TUD treatment by clinicians working within outpatient community mental health settings. The Smoking Knowledge, Attitudes, and Practices (S-KAP) instrument (Delucchi et al., 2009)was used to assess provider practices and related factors, including provider knowledge, attitudes and beliefs, and perceived barriers. We observed two primary sets of findings. First, the psychometric properties for the S-KAP described by Delucchi et al. (2009) did not apply to the present data and required the specification of a new factor structure. Second, we observed that providers' ethical commitment to providing TUD treatment and their perceptions of their skills in providing these services emerged as the most important correlates of their self-reported TUD treatment practices.

Focusing on the first set of findings, several of the scales did not have the same reliability as first reported by Delucchi et al. (2009). We also found that while two of the five factors had a relatively good fit to the data (Practices and Knowledge), items from the other three factors appeared to be indicators of multiple underlying dimensions. Utilizing CFA, we pooled the items from these factors and constructed new latent variables for patient, setting, and clinician characteristics, which represented an improved fit to the data. There are at least two possible explanations for the variability in the measurement structure of the S-KAP between the present study and the Delucchi et al. (2009) study. First, the present sample included clinicians who primarily treat mental health conditions such as depression, anxiety, and psychotic disorders, whereas the original study sample were primarily treating substance use disorders. Although there is likely overlap in beliefs and practices related to tobacco use between these two groups, it is plausible that this difference influenced responding on the S-KAP. Second, temporal effects may also underlie differences between the studies given the ten years that have passed since Delucchi and colleagues created the S-KAP.

Focusing on the second set of findings, through the use of SEM-based CFA, we evaluated which of the latent variables were associated with Practices. Only two of the clinician latent variables (Skills and Ethics) were predictive of practices, whereas the Setting and Patient latent variables were not. These results suggest that clinicians with an increased self-perception of their skills and obligation to provide TUD treatment to their clients are more likely to do so. Although the observed association between clinician skills and practices is consistent with prior reports (Chen et al., 2018), other findings are discordant with past research. Specifically, Evers-Casey, Schnoll, Jenssen, and Leone (2019) found an association between anticipated patient outcomes and practices in primary care, whereas we did not observe this relationship. Additionally, we did not observe that a belief that TUD treatment would negatively impact mental health or staff smoking status were associated with smoking practices, although both have been previously described as important predictors (Delucchi et al., 2009). In contrast, the results concerning a perceived ethical obligation to treat TUD represent new data that suggests a possible growing recognition of the importance of providing TUD treatment within community mental health settings. This could be a novel target for interventions designed to improve clinician adherence to guidelines for the treatment of tobacco use by developing an overarching organizational commitment to addressing TUD (Ziedonis et al., 2007).

Several study limitations should be acknowledged. First, we utilized CFA in an exploratory manner and the available data did not allow for the opportunity to cross-validate the model. The stability of the factor



Fig. 1. Final Model Predicting TUD Treatment Practices.

structure should be evaluated with follow-up data from the larger trial, as well as independent studies. Second, the use of cross-sectional data limits causal inferences. While these findings suggest that a greater commitment to providing TUD treatment services was associated with a greater provision of services, alternative interpretations are possible. For instance, clinicians who engage in more TUD treatment practices because they received more training may have, as a consequence, come to believe that TUD treatment is a priority, whereas clinicians with less self-efficacy may minimize the importance of TUD treatment. That is, behavior may drive clinician beliefs more than beliefs drive behavior. However, the association between clinician ethics and practices remained even after controlling for clinician perceived skills, suggesting that beliefs were relevant to practices independent of self-efficacy. In addition, a "third variable" interpretation of these findings might hypothesize that a personality trait (e.g., conscientiousness) drives both more commitment to TUD treatment and actually providing those services. The current study was not designed to evaluate this hypothesis. Third, the data were self-reported and neither independent nor objective verification of actual TUD treatment practices were assessed, raising concerns about measurement error.

# 5. Conclusions

In addition to providing further evidence that mental health clinicians' self-efficacy in providing TUD treatment is associated with actual treatment provision, clinician ethics emerged as a novel correlate. That is, clinicians who reported an ethical commitment to prioritize TUD treatment reported doing so even independent of available resources, training level, or anticipated patient outcomes. While it is not possible to draw causal conclusions about this construct without further evaluation, the present study offers insight into the identification of potentially important targets for intervention within outpatient mental health clinics to increase the provision of TUD treatment for people living with SMI.

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# 7. Contributors

Scott D. Siegel, J-P Laurenceau, Naja Hill and Robert Schnoll helped conceptualize this paper, analyze the data, and draft the manuscript. Alex Flitter oversaw data collection. Robert Gross and Frank Leone ensured participant safety, helped with participant recruitment, and edited this manuscript. Robert Schnoll served as the overall study Principal Investigator, conceptualized the present study, handled some of the analyses, and co-drafted the manuscript. All authors reviewed the manuscript for content and have approved the final version.

# **Declaration of Competing Interest**

Dr. Schnoll received medication and placebo free from Pfizer and has provided consultation to Pfizer, GlaxoSmithKline, and Curaleaf. Dr. Beidas receives royalties from Oxford University Press and has provided consultation to Merck and the Camden Coalition of Healthcare Providers.

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