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Does the Presence of a Smoking Cessation Clinical Trial Affect Staff Practices Related to Smoking?

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Abstract

This study investigated whether organizational changes occurred when nicotine treatments were tested in specialty care clinics. Two intervention clinics (one drug treatment and one HIV-care) participated in clinical trials for nicotine treatment. Three clinics (two drug and one HIV-care) were control clinics. Staff in the intervention clinics ($n=57$) and in the control clinics ($n=62$) were surveyed at baseline and 18 months later. Staff surveys concerned nicotine-related knowledge, beliefs about treating smoking, self-efficacy in delivering such treatment, nicotine related practices, and barriers to providing nicotine treatment. Mean scale scores at 18 months were no different in clinics participating in the clinical trials from the control group for any of the five scales (knowledge, practices, barriers, efficacy, and beliefs). The presence of a smoking cessation clinical trial did not influence staff knowledge, attitudes, or practices related to smoking in these clinics. More specific organizational intervention may influence staff practices related to addressing smoking among clients in drug treatment and HIV-care clinics.

Introduction

Research has shown elevated smoking rates among special populations with existing healthcare needs, including substance abuse and HIV infection (Kalman, 1998; Mamary, Bahrs, & Martinez, 2002). Studies of persons with substance abuse problems report that 60% to 100% of those in treatment smoke (Burling, Ramsey, Seidner, & Kondo, 1997; Kalman, 1998), that substance abusing persons who smoke are more heavily addicted to nicotine than other smokers (Hughes, 2002; Sobell, 2002), and that alcohol-dependent individuals die from smoking-related causes more frequently than from alcohol-related causes (Hurt et al., 1996). Smoking prevalence among persons living with HIV is also higher than that in the general population (Sobell, Sobell, & Agrawal, 2002), and higher than that among HIV negative persons (Burns et al., 1991; Craib et al., 1992). Smoking predicts HIV-related medical complications for those living with HIV (Diaz et al., 2000), and psychosocial factors associated with smoking cessation failure (e.g., negative affect, stress) may be more prevalent among persons with HIV (Demas, Schoenbaum, Wills, Doll, & Klein, 1995). There are benefits to quitting smoking for persons with these co-occurring conditions. Smoking cessation has been associated with recovery from alcohol abuse (Sullivan & Covey, 2002), and reduced alcohol consumption has been associated with successful smoking cessation (West, 2001). Smoking cessation is a recommended medical priority for persons living with HIV (Hirschtick et al., 1995).

Despite the benefits of smoking cessation, smoking behavior is frequently overlooked in healthcare settings (Frazier et al., 2001). Studies of healthcare professionals in a range of

clinical settings have investigated factors that facilitate or impede the provision of nicotine dependence treatment. Attitudinal barriers include low outcome expectations and low self-efficacy (Borrelli et al., 2001; Tremblay et al., 2001), perceived lack of patient interest (Krupski et al., 2002; Simoyan, Badner, & Freeman, 2002), and low priority given to smoking cessation among competing healthcare needs (Pollak et al., 2001). Structural or organizational barriers include time constraints and the failure of insurance companies to reimburse smoking cessation counseling (Krupski et al., 2002; Simoyan, Badner, & Freeman, 2002). These difficulties may be part of the larger problem of translating scientific advances into improved clinical practice and can be conceptualized in terms of organizational change. In this paper, we explore the questions of whether clinics participating in clinical trials of smoking cessation experienced organizational change regarding smoking practices.

There are reasons that participation in clinical trials may influence organizational practices. For example, in a national survey of drug treatment programs, Fuller et al., (2007) found that the provision of smoking cessation services was related to more positive staff attitude toward smoking cessation. If a clinical trial brings smoking cessation services into a clinic setting, then the presence of those cessation services may also affect staff attitudes toward smoking. When clinics participate in clinical trials of any intervention, staff are exposed to the intervention, some may be trained to provide the intervention or they may hear about the intervention frequently as part of recruitment strategies, and through their work with clients they can observe any impacts of the intervention in their specific clinic setting. These are theoretically relevant factors in diffusion research, related to adoption of new practices (Backer, 1995; Rogers, 2002; Simpson, 2002). A small body of literature has commented on the role that clinical trial research may have in changing clinical practice (Fals-Stewart, Logsdon, & Birchler, 2004; Glasgow, Lichtenstein, & Marcus, 2003; Guydish, Tajima, Manser, & Jessup, 2007).

This study assessed whether clinics participating in clinical trials of smoking cessation interventions experienced organizational change, measured through changes in staff knowledge, attitudes, practices, efficacy, and barriers related to smoking cessation intervention. Staff in two clinics participating in smoking cessation clinical trials were compared to staff in three comparison clinics (where no smoking cessation clinical trial was implemented) over 18 months. The hypothesis was that clinical trial participation would produce increased knowledge of nicotine dependence and its treatment, more favorable beliefs about treating smoking in these settings, greater self-efficacy in providing such treatment, improved clinical practices related to smoking, and decreased barriers to providing smoking cessation intervention.

Methods

Study Design

This is a longitudinal descriptive study of two groups: the intervention group (staff in two clinics hosting a smoking cessation clinical trial) and the control group (staff in three clinics not hosting a smoking cessation clinical trial). Study groups were surveyed at two time points and compared on five outcome measures: knowledge of smoking risks, beliefs about addressing smoking in their clinical setting, self-efficacy in addressing smoking with clients, smoking intervention practices that they use, and barriers to providing smoking cessation services.

Description of Clinical Trials

The study reported here is concerned with whether the presence of a smoking cessation clinical trial impacts how staff in those clinics address smoking with their patients, and the specific

features of the clinical trial are less important. However, the clinical trials are briefly described below.

The clinical trial for persons in substance abuse treatment was conducted in a hospital-based Veteran's Administration (VA) substance abuse treatment clinic. Participants were at least 18 years of age, were current smokers who were interested in quitting, and used alcohol as their primary drug of abuse but were abstinent from alcohol for at least one week and not more than six months at the time of recruitment. Participants were randomly assigned to receive either standard smoking cessation intervention in the clinic or an intensive smoking cessation intervention with six-month extended cognitive-behavioral therapy and combination nicotine replacement (a choice of adjuvant lozenges, gum, nasal spray, or inhaler to be used along with the patches).

The clinical trial for persons enrolled in HIV-care was conducted in an HIV-care clinic located in a county general hospital setting. Participants were HIV-positive smokers enrolled in the clinic, at least 18 years of age, who reported smoking "on most days" in the past month and who were interested in quitting smoking. Participants were randomly assigned to receive either 1) a manualized six session individual counseling intervention focused on education, mood management and social support, 2) a computer-based intervention where the same content was delivered via internet, or 3) a minimum contact control condition involving brief advice and a self-help manual. All participants had access to nicotine replacement therapy. In both trials, point-prevalence smoking status was compared between groups at three, six, nine, and 12-months post-baseline. The host clinics served as points of recruitment, and staff could refer patients to the study, but all other study activities (recruitment, consent, intervention, and follow-up) were conducted by a study team that was not part of the clinic staff.

Survey Participants

In the two intervention clinics (one substance abuse treatment and one HIV-care clinic) and the three additional clinics (two substance abuse treatment and one HIV-care) all current paid staff (both administrative and clinical) were eligible for inclusion. Volunteer staff, ex-employees, and members of the boards of directors were excluded. A total of 57 staff members were recruited from the intervention clinics and 62 were recruited from the control clinics. Survey completion rates were 82% at baseline and 90% at 18 months.

Measures

The survey was brief and self-administered and included questions in following areas: (1) demographic characteristics, (2) nicotine dependence, (3) knowledge of nicotine dependence and its treatment, (4) attitudes toward treating nicotine dependence including efficacy, beliefs, and barriers, (5) nicotine-related clinical practices.

Demographic and Employment Characteristics

Participants were asked to report their age, race/ethnicity, levels of education, full-time employment status (yes/no), whether they are certified or licensed (yes/no), addiction recovery status (yes/no), number of years working in the current agency, number of years in the current position, number of years in the field, active caseload per month, and number of patients per week.

Nicotine Dependence

Smoking status, including current smoking status (yes/no) and whether respondents had ever smoked, was assessed using a self-reporting measure (yes/no) and the six-item Fagerström Test for Nicotine Dependence (FTND) (Heatherton, Kozlowski, Frecker, & Fagerström, 1991). The

FTND assesses severity of nicotine dependence through questions such as “Which cigarette would you hate to give up?” (response options are the first cigarette of the morning or all others), and “Do you smoke when you are so ill that you are in bed most of the day?” (Yes/No). Item responses are scored from 0 through 3, and are summed to give an overall assessment score of nicotine dependence, where greater than 6 indicates high nicotine dependence, and 4 to 5 indicates moderate nicotine dependence.

Smoking Knowledge, Attitudes, and Practices (S-KAP)

The survey was composed of 50 items used from previous studies (Borrelli et al., 2001; Goldstein, DePue, & Monroe, 1998; Velasquez et al., 2000), and from a review of papers reporting staff surveys related to smoking in drug treatment settings (Guydish, Passalacqua, Tajima, & Manser, 2007). Knowledge of nicotine dependence was measured by the level of agreement with statements based on questions from the Centers for Disease Control and Prevention (CDC) Adult Tobacco Survey (Centers for Disease Control and Prevention, n.d.) and the California Adult Tobacco Survey (California Department of Health Services, 2004). Practice items included use of the National Cancer Institute four A's (Ask, Advice, Assist, Arrange follow up), recommended for use by providers to address smoking with their patients (Glynn & Manley, 1989). This is an earlier version of the current five A's approach, which includes assessment of patient readiness to quit (Fiore et al., 2000, 2008). Exploratory factor analyses were used to examine the underlying factor structure of the items, which coalesced into five factors. The five factors were labeled knowledge, beliefs, self-efficacy, practices and barriers (see also Delucchi, Tajima, & Guydish, in press).

Knowledge Scale

Participants were asked their level of agreement with the following: whether smoking increases the risk of heart attack, results in poor wound healing, and causes other health problems, whether the risks of smoking and second hand smoke have been clearly demonstrated, and whether HIV positive status increases the risk of developing smoking-related illness.

Beliefs Scale

Participant's reported their level of agreement with the following statements: “Smoking cessation counseling is an important part of my agency's mission” and “Smoking is a personal decision which does not concern the clinician.” Respondents were asked the best time to encourage patients to stop smoking, and whether they should quit other drug use before quitting smoking.

Self-efficacy Scale

Participants indicated level of agreement with statements such as “I have the required skills to help my patients quit smoking” and “I know where to refer patients for help with smoking cessation.” Respondents were also asked what percent of their patients would try to quit smoking and what percent would succeed in quitting, if counseled to do so by their counselor, and how confident they are in their ability to address smoking with their clients.

Practices Scale

Participants were asked how often, in the past month, they had asked patients about smoking, advised patients to quit, assisted patients with quitting, or arranged follow-up visits to discuss quitting. Respondents also reported how often they encouraged patients to stop smoking, to use nicotine replacement therapy, or to avoid smoking around children.

Barriers Scale

Respondents were asked whether they were able to tailor smoking cessation counseling to individual patient needs, and they gave reasons that limited their ability to offer smoking cessation services. These reasons, rated on a scale from “not at all important” to “very important”, included that patients are not interested in smoking counseling, that there is a lack of staff time, staff training, or patient education materials to support smoking cessation counseling, or that other health problems require more immediate attention.

Survey Procedures

A site research liaison provided a list of all eligible staff members with the study team and scheduled lunchtime staff meetings in each clinic. In the staff meetings, the nature of the survey was introduced and explained, consent procedures were completed, and participants were invited to complete the survey. Each participant received a study packet consisting of a survey, informed consent sheet, and stamped and addressed envelope. Staff members who agreed to participate returned their completed survey and signed consent forms by mail or by handing the envelope to the site research liaison after the staff meetings.

Staff decisions to participate in the study were confidential. To protect their confidentiality, staff members were given the choice of telling the research team members directly or returning a blank survey and indicating “decline to participate.” Research records of surveys were also confidential. Each participant was assigned a unique identification number, which appeared on the survey in the top right corner. For staff members who were absent from these meetings, the packets were distributed by mail. Staff members received a \$25 gift card for their participation. All study procedures were approved by the Institutional Review Board at the University of California, San Francisco.

Data Analysis

The data analysis plan included three steps. First, the two conditions (intervention vs. control) were compared on demographic characteristics such as gender, ethnicity, education, full-time/part-time position, current smoking status, history of smoking, number of years working in the current agency and the field, active caseload per month, and number of patients per week.

Second, in order to assess changes in smoking measures (knowledge, practices, barriers, efficacy, and beliefs) over time, the scale mean scores at the 18-month follow-up were compared between the two conditions (intervention vs. control) using parametric linear modeling estimated via restricted maximum likelihood using Proc Mixed in SAS v9.1.3. The models of each outcome included three parameters. These were two conditions (intervention v. control) and two control covariates: a) whether the clinic was HIV-focused or not and b) the baseline value of the dependent variable (each smoking scale). By including the baseline value of the outcome variable, baseline differences were statistically controlled. Using maximum likelihood estimation allowed the inclusion of all available data in the estimation of the model parameters, avoiding listwise deletion of respondents and the resulting bias if the data were not missing completely at random. In addition to those who responded at only one assessment, all staff—regardless of position—were included in these analyses, because participation in a clinical trial related to smoking could potentially influence outcome measures (with the exception of practices) for non-clinical as well as clinical staff. There were a total of 119 respondents at baseline and 124 at follow-up, and 96 were present at both time points.

Third, because the influence may be greater on clinical staff, we identified only those staff having patient care responsibilities and re-ran analyses with this subgroup. Participants were classified as non-clinical staff if they reported a non-clinical title in the agency and their reported weekly client contact hours and caseload were both less than or equal to five. Non-

clinical titles were administrator, program director, training coordinator, intake administrator, any research title, or “other.” There were 89 clinical staff respondents at baseline (75% of the total at baseline) and 95 at follow-up (77% of the total at follow up), and 71 were present at both times. In all analyses the statistical models incorporated an indicator of clinic to control for the clustering effect. Staff within a clinic cannot be considered completely independent of each other from a statistical standpoint, and failure to correct for this effect underestimates the variance and biases the *p*-values downward.

Results

Comparison of Study Groups at Baseline

Comparisons between groups at baseline are shown in Table 1. Controlling for clustering within clinics, there were no differences between staff in the interventions and comparison conditions for demographic variables (gender, ethnicity, education), variables related to smoking status or addiction recovery status, or agency employment variables (e.g., full-time/part-time status, number of years working in the current agency and the field, active caseload per month, and number of patients per week). Staff in the two conditions did not differ on mean scale scores for any of the five smoking-related scales measures at baseline (data not shown).

Comparison of 18-Month Outcomes by Condition

The S-KAP staff survey was used to measure five constructs that may show differences between clinics that did and did not host a smoking cessation trial. We hypothesized that, compared to control clinics, staff in those clinics hosting such a trial would show greater knowledge about the hazards of smoking, use more practices to address smoking with clients, perceive fewer barriers to providing tobacco dependence services, report more self-efficacy in the treatment of smoking, and also have more favorable beliefs about addressing smoking in their setting. To assess these hypotheses, mean scale scores for each scale (knowledge, practices, barriers, efficacy, and beliefs) were compared between condition at 18 months, controlling for type of setting (HIV-care, drug abuse treatment) and baseline values on each scale, and accounting for staff clustering within clinics. Results of these comparisons are reported in Table 2, where relevant comparisons were, for example, between the mean knowledge score at 18 months in the intervention group (4.40) and in the control group (4.34), between the mean practice score at 18 months in the intervention group (3.15) and in the control group (2.82), and so on for each of the S-KAP scales. Findings in Table 2 show that there were no significant differences between staff in intervention and control clinics for any of the five scales tested. This suggests that, even though a smoking cessation trial had been ongoing for 18 months in the intervention clinics while none had been ongoing in the control clinics, staff in both conditions showed similar levels of smoking related knowledge, practices, barriers, efficacy, and beliefs, as measured by the S-KAP and after controlling for baseline values. Study hypotheses were not supported.

Findings reported in Table 2 were based on analyses including all program staff, including both clinical and administrative staff. Because clinical staff work more directly with patients than do administrative staff, and would be more involved in addressing smoking as a clinical issue with patients, it is possible that staff smoking knowledge, attitudes, and practices would show greater change among clinical staff. To assess this, analyses were repeated while including only the subset of staff having direct patient-care responsibility. In this subgroup analysis, the results were unchanged (data not shown). The absence of a difference between conditions, in this study, was not due to differential change between clinical and administrative staff.

Discussion

This study assessed whether the presence of clinical trials testing smoking cessation interventions may affect how staff view smoking, and how they address smoking among their clients. Staff in the experimental clinics (where the clinical trials occurred) and in the control clinics (where no clinical trial occurred) were surveyed before the trials began and again 18 months later. Controlling for baseline values and clustering, we observed no difference between intervention and control clinics for measures of knowledge about the risks of smoking, practices used to address smoking with clients, barriers to providing smoking cessation services, self-efficacy in providing such services, or beliefs about whether and when to address smoking. Findings of no difference between conditions were the same in different types of clinics (drug abuse and HIV-care), for all staff, and for the subgroup of staff having clinical responsibilities.

These findings suggest that participation in clinical trials is not sufficient to change how staff address smoking among clients, and so other strategies may be required to support staff in better addressing smoking. Organizational change models have been developed and applied to address smoking cessation in substance abuse treatment settings (Bowman & Walsh, 2003; Hoffman & Slade, 1993; Stuyt, Order-Connors, & Ziedonis, 2003; Ziedonis & Williams, 2003). One manualized intervention along these lines is Addressing Tobacco Through Organizational Change (ATTOC), which is designed to support programs in better addressing smoking at the organizational level (Hoffman et al., 2004, Ziedonis et al., 2007). Beyond the organizational level, suggestions from substance abuse treatment research have included dissemination of clinical guidelines for smoking treatment to all certified counselors, mandatory counselor continuing education on smoking cessation (Hahn, Warnick, & Plemmons, 1999), reimbursing programs for smoking cessation services, and resources to help staff quit smoking (McCool, Richter, & Choi, 2005). Less has been written with respect to addressing smoking in HIV-care settings, but many of the same suggestions may be suitable.

Limitations of this research concern generalizability, limited sample size, the use of new measurement scales, and possible ceiling effects in VA settings. Because clinical trials differ in their procedures and in the level of involvement required of program staff, findings reported here may not generalize to other clinical trials or to other clinics. In particular, staff involvement in these clinical trials was limited to learning about the trial, participating in a recruitment meeting, use of printed referral information developed for clients, and referring clients to the study. Had staff been directly involved in conducting smoking cessation intervention for the clinical trial, results may have differed. The study included five clinics and 119 staff members at baseline. While data were collected at the individual (staff) level, differences in mean scores were compared at the condition level, with two to three clinics per condition. Analyses included controls for clustering of staff within clinics, and these procedures resulted in appropriate but conservative estimates of difference. Studies involving larger numbers of staff and clinics may result in different findings. The staff survey measures were based on prior similar surveys, and scales were developed based on factor analyses (Delucchi et al., in press). Prior research using staff survey methods in this area has relied on analysis of individual items, and the use of scales should afford improved measurement of underlying constructs. However, because these scales are new, there is no published research demonstrating their usefulness in measuring change over time. Finally, VA medical centers have well developed policies and procedures for addressing smoking among all patients, including those in substance abuse treatment (Isaacs, Schroeder, & Simon, 2004), and this may create ceiling effects with regard to the measures used here, limiting ability to observe additional impacts of smoking-related clinical trials in those settings. While understanding these limitations, to our knowledge this is the only paper that reports on the impact of smoking cessation clinical trials on staff knowledge, attitudes, and practices related to smoking.

In this study and over 18 months, clinic participation in smoking cessation clinical trials did not have an observable impact on how staff perceived smoking or on how they addressed smoking with their clients. Other strategies are needed to support staff in these settings to more effectively address smoking. Such strategies may include specific organizational change interventions like the ATTOC, and/ or training, policy development, financial reimbursement, and smoking cessation interventions directed to program staff, with leadership and coordination through state and national funding and professional organizations.

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Biographies

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Joseph Guydish, PhD, MPH, is Professor of Medicine at the University of California, San Francisco. His research is in the area of access, delivery, and organization of substance abuse treatment services, treatment effectiveness, and adoption of new treatments into practice settings. He is currently testing strategies designed to support drug abuse treatment programs in better addressing nicotine dependence.

Kevin Delucchi, PhD, is Professor of Biostatistics in Psychiatry at the University of California, San Francisco. His primary field of research is the application of statistical methods to studies of drug and alcohol abuse.

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Table 1

Comparison of Participant Characteristics, by Condition, at Baseline (n=119)

	Intervention (n = 57)	Control (n = 62)	p-Value
Gender (% , n)			.218
Male	39 (22)	31 (19)	
Female	61 (34)	69 (43)	
Ethnicity (% , n)			.381
White	58 (33)	53 (33)	
African American	12 (7)	31 (19)	
Other	30 (17)	16 (10)	
Education (% , n)			.853
Completed high school/GED	5 (3)	3 (2)	
Some college	11 (6)	13 (8)	
Associate	4 (2)	15 (9)	
Bachelor's	16 (9)	18 (11)	
Master's	34 (19)	28 (17)	
Doctorate	30 (17)	23 (14)	
Full-time employee, Yes (% , n)	82 (47)	77 (48)	.469
Current smoker, Yes (% , n)	7 (4)	5 (3)	.522
Ever smoked, Yes (% , n)	47 (25)	50 (30)	.686
Certified/licensed (% , n)	20 (11)	13 (8)	.665
In recovery (% , n)	9 (5)	11 (7)	.253
Years in agency (mean, SD)	10.2 (8.7)	12.94 (13.7)	.670
Years in position (mean, SD)	7.6 (6.8)	10.02 (13.6)	.553
Years in addiction treatment (mean, SD)	10.8 (8.9)	12.18 (14.8)	.515
Years in HIV treatment (mean, SD)	9.0 (8.3)	10.660 (14.4)	.996
Active caseload per month (mean, SD)	77.7 (101.4)	112.59 (138.7)	.955
Number of patients per week (mean, SD)	23.0 (20.3)	29.88 (23.5)	.524

* Pearson chi-square tests were used to assess differences for categorical variables and t-tests were used for continuous variables.

Table 2
Means and Standard Deviations for Scale Scores by Time and Condition, For All Staff

Scale	Intervention		Control		p-value*
	Baseline (n=57)	18-Months (n=60)	Baseline (n=62)	18-Months (n=64)	
Knowledge	4.36 (0.61)	4.40 (0.50)	4.25 (0.76)	4.34 (0.63)	.292
Practice	3.28 (1.02)	3.15 (1.12)	2.70 (1.03)	2.82 (1.12)	.781
Barriers	1.78 (0.66)	1.68 (0.74)	1.92 (0.67)	1.96 (0.66)	.140
Efficacy	3.40 (0.53)	3.45 (0.62)	3.25 (0.70)	3.20 (0.54)	.377
Beliefs	4.07 (0.62)	4.05 (0.63)	3.89 (0.67)	3.83 (0.61)	.288

* Mean scale scores at 18 months were compared between groups, controlling for baseline scale and type of program (HIV care clinic or drug abuse treatment clinic). Statistical models incorporated an indicator of clinic to control for the effect of staff clustering within clinic.