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Opioid treatment programs in the Clinical Trials Network: Representativeness and buprenorphine adoption

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Abstract

As the Clinical Trials Network begins to focus efforts on disseminating the results of its research studies to the addiction treatment field, it is important to begin to assess the capacity of programs outside the CTN to integrate with fidelity these endorsed treatment practices. To date, no data exist to assess the representativeness of opioid treatment programs (OTPs) participating in the CTN, nor the potential barriers to the effective diffusion of practices aimed at the treatment of opioid dependent patients, including buprenorphine. Using data obtained from OTPs within the CTN (N=49) and a sample drawn from the population of U.S. OTPs (N=50), this study compares the two groups on their organizational, clinical, and client characteristics, as well as their adoption of buprenorphine. The study finds that the populations differ significantly on numerous variables, but that structural characteristics appear more predictive of buprenorphine adoption than either staff or caseload differences. Implications for studying the diffusion and implementation of evidence-based research findings are discussed.

1. Introduction

In 1999, the National Institute on Drug Abuse (NIDA) launched a unique research-provider collaborative known as the National Drug Abuse Treatment Clinical Trials Network (CTN). The CTN has two principal objectives (Hanson, Leshner & Tai, 2002). First, it is a platform for rigorous, multi-site clinical trials of evidence-based psychosocial and pharmacological therapies for addiction treatment across a variety of providers that vary in their organizational structure, staffing, client caseload, and treatment service delivery approaches. Thus, in contrast to clinical trials conducted in research hospitals or in a small set of homogenous settings, treatment techniques found to be effective within the CTN's collection of "real world" treatment providers should be readily translatable to community based treatment programs outside the CTN. Thus the strategy should increase efficiency in technology transfer and in bridging the research-to-practice gap. This embodies the CTN's second objective: taking those practices showing promising results in CTN clinical trials and actively facilitating their dissemination to the broader treatment field.

Underlying these efforts is the assumption that the collection of community-based treatment providers (CTPs) in the CTN is indeed reflective of programs in the "real world." As findings from the CTN's initial clinical trial protocols begin to be disseminated, it becomes imperative

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to understand whether the intended audience of these dissemination efforts resembles the treatment settings in which these approaches have been demonstrated to be effective. If these assumptions are invalid, then treatment providers outside the CTN may not be able to integrate these evidence-based practices into their own programs, or at least not without making significant adaptations that may threaten the effectiveness of the technology and, in effect, void the warranty conferred by the CTN. Thus, to guide dissemination efforts, valid data on the comparability of CTN and non-CTN treatment providers are needed. A further worthwhile area of research is whether affiliation with the CTN generally, and exposure to clinical trial protocols specifically, renders CTN-affiliated programs more likely to adopt innovative treatment techniques, and whether this exposure has an additive effect beyond any systematic differences in the organizational structure of programs within versus outside the CTN.

Several recent articles have begun to describe the composition of the organizations and clinical workforce in the CTN (McCarty et al., 2008; McCarty et al., 2007). These and other data sources have allowed for an assessment of the representativeness of psychosocial counseling-oriented CTPs versus those outside the CTN (Ducharme, Knudsen, Roman & Johnson, 2007), as well as the characteristics of counselors working in CTN-affiliated and non-CTN sites in the public and private sectors (Knudsen, Ducharme & Roman, 2007). There appear to be significant differences between psychosocial counseling-oriented programs within and outside the CTN on a number of organizational characteristics, including profit status, accreditation status, access to medical staff, hospital location, and availability of short-term detoxification services. However, to date, there has been no direct assessment of the representativeness of the opioid treatment programs (OTPs) within the CTN – a topic meriting examination given the number of CTN trials focused on treatment techniques with direct relevance for opioid dependence treatment.

Likewise, although prior research has shown CTN involvement to be positively associated with both program-level adoption of buprenorphine (Ducharme et al., 2007), as well as counselor attitudes toward buprenorphine (Knudsen et al., 2007), there has until now been no data available with which to identify and explain differential organizational uptake of buprenorphine in OTPs within and outside the CTN. This article fills that void by reporting the findings of a study directly comparing CTN and non-CTN OTPs.

2. Methods

Two studies contributed data to these analyses. The first was a NIDA-funded study that surveyed the population of CTPs to document their experience in the CTN, their exposure to various clinical trials, and their adoption of treatment techniques supported by those trials. (The objective and methods of the study are described in greater detail in Ducharme et al., 2007.) A total of 215 CTPs participated in the study (96% response rate). The CTN sample contributed 49 OTPs to the analyses described here.

To assess the representativeness and innovativeness of the CTN OTPs, a second study was undertaken to gather data from a sample of OTPs outside the CTN. The sampling frame for this study was derived from the treatment facility locator maintained by the Substance Abuse and Mental Health Services Administration (SAMHSA). First, all OTPs were identified within the 2005 facility list. From these, all CTN-affiliated OTPs were identified and excluded. Next, OTPs that were not “community based” (i.e., correctional facilities) were excluded. Finally, OTPs that offered only detoxification services were excluded. This resulted in a final sample frame of N=958 community-based, non-CTN OTPs. From these, a simple random sample of 50 OTPs was drawn. Sampled OTPs were recruited into the study, and refusals were replaced by randomly sampled programs until the target sample of 50 units was achieved. The final

sample reflects an 83% response rate (60 sites invited to participate in order to obtain 50 respondents).

Data were collected from both samples via face-to-face interviews with program administrators and clinical directors. With the exception of some CTN-specific questions asked only of the CTN OTPs, the interview protocols in both studies were identical. Data collection for both studies spanned the calendar year 2006. Participating programs were paid an incentive of US \$100. The University of Georgia's Institutional Review Board reviewed and approved the research protocol for both studies.

2.1 Measures

Several variables were examined to assess the comparability of the samples on organizational, staff, and client characteristics. *Profit status* is a dichotomous variable, with for-profit OTPs coded 1 (zero otherwise). Two measures of program size are used: *total number of employees*, and *census* on the day of the interview. Two characteristics of program staff are used as indicators of the OTP's relative ability to integrate buprenorphine into treatment: *number of nurses* on staff, and percent of *counselors holding at least a Master's degree*.

Two indicators of the treatment milieu are included. The *average length of stay* of clients in the OTP is measured in weeks. The proportion of clients maintained (stabilized) on methadone *doses of less than 60 mg/day* is also included. As demonstrated by D'Aunno and colleagues (D'Aunno, Folz-Murphy & Lin 1999; D'Aunno & Vaughn 1992; D'Aunno & Pollack 2002; Pollack & D'Aunno in press), the prevalence of "low dose" clients may be an indicator of program quality, and may also be associated with program management's commitment to a medication model. This, in turn, may impact their willingness to adopt buprenorphine.

Four variables characterize the populations in treatment at these programs. The percentages of *Medicaid clients*, *self-paying clients*, *unemployed clients*, and *clients involved in the criminal justice system* (probation, parole, or drug courts) are used as indicators of ability to pay for buprenorphine. Decision-makers in OTPs serving proportionately more clients who are dependent on public funding sources may perceive that they have less of a viable market for this comparatively expensive medication among their treatment population, and thus be less likely to adopt it. In prior analyses of addiction treatment programs, such variables have been significantly associated with program adoption of pharmacotherapies (Ducharme & Abraham, 2008; Ducharme, Knudsen & Roman, 2006; Heinrich & Hill, 2008; Thomas, Wallack, Lee, McCarty & Swift, 2003).

Adoption of buprenorphine is a dichotomous variable indicating whether the OTP was treating at least one opioid dependent client with buprenorphine on the date of the interview. Sampled OTPs had different arrangements for delivering buprenorphine. The majority (75.7% of adopters) had a credentialed (i.e., waived) physician on staff; 12% had formal referral relationships with a local office-based physician to prescribe buprenorphine to the OTP's clients; and 12% dispensed buprenorphine in the same manner as methadone. Because of the small sample size involved, further analyses within these categories were not undertaken. It should also be noted that adoption of buprenorphine is a concept distinct from implementation. Adoption considers only whether the OTP has begun using buprenorphine for some of its clients; implementation addresses the manner and regularity with which the medication is prescribed. The focal outcome for these analyses is medication adoption.

CTN involvement is controlled for using two dichotomous variables. *CTN affiliation* is coded 1 if the OTP was in the CTN, and zero otherwise. *CTN trial involvement* is coded 1 if the OTP was a participant in one of the CTN buprenorphine clinical trials, and zero otherwise. Together these two variables will allow for an assessment of the effect of each independent variable on

buprenorphine adoption net of the influence of exposure to the CTN generally or buprenorphine trials specifically.

3. Results

3.1. Descriptive Statistics

Data from the two studies were pooled for analysis. Frequencies for the study variables are shown in Table 1, along with results of tests for significance of between-sample differences.

As shown, the samples differ significantly on all variables. As with counseling-oriented programs (McCarty et al., 2008), a greater proportion of OTPs outside the CTN operate as for-profit units. This percentage better reflects the OTP population – SAMHSA's national data indicated that, in 2006, 45.1% of the nation's OTPs operated on a for-profit basis (SAMHSA, 2007). OTPs in the CTN are significantly larger, as reflected in the average number of employees, nurses, and clients (census). CTN OTPs employ more Master's level counselors, suggesting a reliance on more professionalized staff, which appears to be a characteristic of the CTN generally (Knudsen et al., 2007; McCarty et al., 2007), and may be partly a function of selection bias in the composition of participating nodes. OTPs within the CTN report significantly shorter average lengths of stay, and a higher percentage of clients receiving daily methadone doses under 60 mg. Finally, OTPs in the CTN appear to have more indigent clients (unemployed or relying on Medicaid), and treat more clients who are involved in the criminal justice system.

Program-level adoption of buprenorphine was significantly higher among OTPs in the CTN (42.8%) than outside it (24%). In all, 33 OTPs in the pooled sample (33%) reported using buprenorphine at the time of the interview.

3.2. Multivariate Analyses

Because of the small absolute number of programs that reported using buprenorphine, the ability to estimate multivariate models is limited. At least 8 occurrences of the dependent variable are needed to support each independent variable in a logistic regression equation (Cepeda et al., 2003). For this reason, a series of logistic regression models was estimated, each including 3 independent variables: the predictor variable of interest, and the 2 dummy variables controlling for the OTPs' CTN affiliation and their involvement in one of the CTN buprenorphine clinical trials.

In light of our interest in the effect of CTN involvement on organizational behavior, it should be noted that the absolute number of CTN OTPs having participated in a buprenorphine trial as of 2006 was quite small, and thus this variable is not expected to achieve statistical significance in the models.

Nevertheless, its inclusion is needed to at least partially address questions about the effects of participating in the CTN generally versus participating in a clinical trial specifically. Put differently, if the CTN affiliation variable in these models is significant, the effect can be attributed to CTN membership (or CTN composition), and not to the unique effect of hands-on experience obtained in a buprenorphine trial.

The results of 12 logistic regression models are summarized in Table 2. In this table, each row represents a separate model, with three variables included as predictors of buprenorphine adoption. Significant odds ratios for the two CTN variables (CTN membership and buprenorphine clinical trial participation) are shown in each row, along with significant odds ratios for a different organizational characteristic that is included in each model. Power calculations indicate that the sample size of N=99 OTPs is sufficient to detect a medium effect

size in multivariate models with 3 predictor variables, an alpha of .10, and power=.80 (Cohen, 1988).

Despite significant differences in the independent variables between the two samples, only three are significant once CTN involvement is controlled. For-profit OTPs were 2.4 times more likely to have adopted buprenorphine than nonprofit or government-owned facilities. As an indicator of size, program census was inversely associated with buprenorphine adoption. Converting the odds ratio for the census variable into a more intuitive association, we find that an increase of one standard deviation in the number of clients was associated with a 31% decrease in the likelihood of buprenorphine adoption (formula = $100 * [e^{(\beta)(sd)} - 1]$; $\beta = -.002$, $sd = 189.16$). OTPs with more “low dose” methadone clients were more likely to have adopted buprenorphine; specifically, an increase of one standard deviation in the percentage of clients maintained at less than 60 mg/day was associated with a 39.2% increase in the odds of adopting buprenorphine ($\beta = .065$, $sd = 13.42$).

CTN affiliation was significantly associated with buprenorphine adoption in five of the models. CTPs were just over twice as likely to have adopted buprenorphine relative to non-CTPs in the models controlling for profit status and staff (employees, nurses, and Master's level counselors). CTN OTPs were more than three times more likely to have adopted buprenorphine when controlling for program census. However, when controlling for the clinical (dosing, length of stay) and client characteristics, the CTN affiliation variable had no significant effect on the likelihood of buprenorphine adoption.

As expected, given the small number of affected programs, involvement in a buprenorphine clinical trial is not significant in any of the models. Still, including this variable lends support to the conclusion that the CTN affiliation variable, when significant, is capturing differences between the two samples of programs exclusive of first-hand exposure to buprenorphine in a CTN trial.

4. Discussion

A comparison of several structural, staff, and client characteristics suggests that the OTPs participating in the CTN are not representative of the population of community-based OTPs operating in the U.S. as of 2006. In contrast to other modalities (i.e., psychosocial counseling programs), OTPs in the CTN differ from those outside it on numerous measures. In addition to being significantly larger (e.g., number of employees, program census), CTN OTPs exhibit different clinical and caseload characteristics compared to those outside the CTN.

Differences between the two groups are not necessarily problematic unless these differences systematically influence OTPs' ability to adopt and implement with fidelity the treatment practices tested by the CTN and disseminated to the field. On this point, our data show mixed but intriguing results. An OTP's CTN affiliation was significantly associated with the likelihood of adopting buprenorphine when controlling for each of the structural variables (profit status, size, and staff). In each case, net of the effect of the structural variable measured, OTPs in the CTN were 2 to 3 times more likely to have adopted buprenorphine relative to OTPs outside the CTN. By contrast, CTN OTPs were no more likely than those outside the CTN to have adopted buprenorphine after controlling for each of the clinical and caseload variables. Taken together, these findings suggest that, although OTPs in the CTN differ significantly from the population on a number of factors, it is their structural characteristics that most strongly influence their adoption of buprenorphine.

While informative, these analyses are constrained by the small sample size and the absolute number of adopting programs. Because only one unique predictor was entered into each model with the CTN variables, it is not possible to identify what it is about CTN membership that is

associated with the use of this pharmacotherapy. However, the pattern of results is consistent with findings from prior research on organizational adoption of medications, namely, that structural characteristics such as profit status, size, and staff credentials are key elements that facilitate or impede adoption behavior.

While these findings provide a clue as to potentially important considerations when developing technology transfer materials, it is essential to note that such findings can only alert us to differences in whether – but not *how* – buprenorphine is used in these programs. Patient-level data were not available to this study, and thus no conclusions can be drawn about the clinical protocols implemented in these settings with regard to buprenorphine. Such research is needed. It may be that the parameters of OTPs' actual implementation of buprenorphine (e.g., linkages with office-based physicians, induction protocols, dosing levels, taper schedules) do not vary in any systematic way between the two samples. That is to say, it remains unknown whether, once adopted, the unique characteristics of CTN sites continue to influence the implementation of buprenorphine. Further research is needed to assess whether, in buprenorphine-adopting programs, the organization's structural characteristics are significantly associated with the manner in which the medication is used. This type of implementation research is needed to understand whether clinical approaches shown to be effective in the CTN are employed with fidelity to tested protocols in adopting programs.

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Table 1
Descriptive statistics: Mean or percent (standard deviation)

	Pooled sample (N=99)	CTN OTPs (N=49)	Non-CTN OTPs (N=50)
Government-operated (% of OTPs)	6.1	4.0	8.0
Private non-profit (%)	54.5	65.3	44.0
Private for-profit (%) *	39.4	30.6	48.0
# Employees **	23.6 (15.7)	30.4	16.8
# Nurses **	3.3 (3.0)	3.7	2.8
% Master's-level counselors **	36.1 (27.8)	42.7	29.5
Census **	334.8 (307.0)	394.7	276.2
Avg length of stay (weeks) **	144.5 (120.0)	123.4	165.1
% Clients < 60mg *	22.7 (20.0)	25.2	20.3
% Medicaid clients **	33.5 (33.0)	44.0	23.1
% Self-pay clients **	39.3 (30.0)	26.6	51.8
% Unemployed clients **	48.8 (50.0)	55.8	41.9
% Criminal justice involved *	27.6 (22.0)	31.9	23.4
Use buprenorphine (percent of OTPs) **	33.3	42.8	24.0

Figures reflect sample mean unless otherwise noted.

**
 $p < .05$,

*
 $p < .10$ (significant between-group differences)

Table 2
Results of logistic regression models of program characteristics and CTN involvement on adoption of buprenorphine

Predictor in model	Odds Ratios (where significant)		
	Predictor	CTN Affiliation	CTN Trial Involvement
For-profit OTPs	2.42	2.58	ns
# Employees	ns	2.37	ns
# Nurses	ns	2.28	ns
% Master's counselors	ns	2.29	ns
Census	.998	3.14	ns
Avg length of stay	ns	ns	ns
% Clients < 60 mg	1.07	ns	ns
% Medicaid clients	ns	ns	ns
% Self pay clients	ns	ns	ns
% Unemployed clients	ns	ns	ns
% Criminal justice involved	ns	ns	ns

Note: Each row represents a separate model. ("ns" = not significant)