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The relationship between Clinical Trial Network protocol involvement and quality of substance use disorder (SUD) treatment

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Abstract

The National Institute on Drug Abuse's Clinical Trials Network (CTN) is a practice-based research network that partners academic researchers with community based substance use disorder (SUD) treatment programs designed primarily to conduct effectiveness trials of promising interventions. A secondary goal of the CTN is to widely disseminate results of these trials and thus improve the quality of SUD treatment in the US. Drawing on data from 156 CTN programs, this study examines the association between involvement in CTN protocols and overall treatment quality measured by a comprehensive index of 35 treatment services. Negative binomial regression models show that treatment programs that participated in a greater number of CTN protocols had significantly higher levels of treatment quality, an association that held after controlling for key organizational characteristics. These findings contribute to the growing body of research on the role of practice-based research networks in promoting health care quality.

Keywords

substance use disorders; treatment; Clinical Trials Network; practice-based research network; quality of care

1. Introduction

In 1999 the National Institute on Drug Abuse's Clinical Trials Network (CTN) was formed to help bridge the research-to-practice gap in substance use disorder (SUD) treatment in response to an influential Institute of Medicine (IOM) report (Lamb, Greenlick, & McCarty, 1998). Much like other specialties within health care, the IOM report noted that the field of SUD treatment was slow to integrate evidenced-based practices (EBPs) into routine practice. The CTN continues to function as a multi-node practice-based research network in which

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academic researchers and community-based SUD treatment program (CTP) leaders collaborate to design and conduct effectiveness trials in diverse, “real world” treatment settings. The CTN focuses largely on interventions that already show promise, and thus, conducts Stage 3 effectiveness trials that seek to establish external validity by utilizing the diverse range of patients who are being treated within CTPs and by training clinicians who are already employed (Tai, Sparenborg, Liu, & Straus, 2011; Wells et al., 2010).

To date, the CTN has completed 27 effectiveness trials and randomized over 15,800 patients. There are currently 17 trials in progress and several more trials in development (Tai et al., 2011). The CTN’s research portfolio has included medications for the treatment of opioid use disorders and smoking as well as psychosocial interventions such as motivational enhancement therapy, contingency management, and brief strategic family therapy. Other protocols have focused on ancillary wraparound services, such as rapid HIV testing, HIV risk reduction interventions, employment services, and an intervention for women with co-occurring trauma and SUDs. (See Tai et al, 2010 and Wells et al., 2010 for a detailed description of completed CTN trials.)

The characteristics of the CTPs within the CTN that have differentially participated in these clinical trials have not been explored, and the relationship between research involvement and overall treatment quality has not been examined. The purpose of this paper is to explore whether research protocol involvement is associated with the provision of comprehensive treatment services and adoption of EBPs. According to common assumptions within the field, particularly those driving the promotion of the use of EBPs, these variables are proxies for higher quality treatment services (NIDA, 2009).

1.1. Practice-based research networks (PBRNs)

The NIDA CTN is part of a genre of practice-based research networks (PBRNs) that first emerged in the late 1970s as an alternative to the tradition of conducting clinical trials in academic health centers. Clinical trials in these academic settings were often seen as disconnected from the health problems encountered by community clinicians and their patients (Macaulay & Nutting, 2006; Smith, Sexton, & Bradley, 2005; Tierney et al., 2007; Westfall, VanVorst, Main, & Hebert, 2006). By contrast, PBRNs consist of collaborations between academic researchers and a group of community-based health care providers with the goal of improving health services delivery and closing the gap between research and practice (Gilbert et al., 2008; Pearce, Love, Barron, Matheny & Mahfoud, 2004; Riedy, Ly, Ybarra, & Milgrom, 2007). In the US, PBRNs span a variety of health disciplines including primary care, dentistry, and mental health (Andrews, Pearce, Ireson, & Love, 2005; Barasch et al., 2012; Buckley, Calvert, Lapidus, & Morris, 2010; McMillen, Lenze, Hawley, & Osborne, 2009; Tapp, Herbert, & Dulin, 2011). According to Onofrie and colleagues (1994), PBRNs are said to be critical in facilitating translational science because they are able to “identify and assess implementation strategies that are most likely to be effective and sustainable (p. 139).”

In addition to their specific contributions to translational science, organizational behavior research indicates that participation in interorganizational networks, of which PBRNs represent a specific type, facilitates the adoption and diffusion of innovations among member organizations (Ahuja, 2000; Erickson & Jacoby, 2003; Gibbons, 2007; Goes & Park, 1997; Pittaway, Robertson, Munir, Denyer, & Neely, 2004; Powell, Koput, & Smith-Doerr, 1996; Rogers, 2003; Westphal, Gulati, & Shortell, 1997). These benefits with regard to innovation appear to result from knowledge sharing, resource exchange, collaboration, and communication that occurs between members of the network. In contrast to affiliative networks such as professional organizations, research networks may provide organizations

with access to new innovations so that they can gain experience with innovations before committing to full-scale implementation (Ducharme, Knudsen, Roman, & Johnson, 2007).

Empirical investigations in other fields have shown that research network involvement is positively associated with innovation adoption in member organizations (Fennell & Warnecke, 1988; Laliberte, Fennell, & Papandonatos, 2005; Minasian et al., 2010). Two studies examining the impact of participation in cancer research networks highlight the value of network involvement in improving implementation of evidence-based care and increasing access to innovative treatment interventions (Carpenter et al., 2011; Laliberte et al., 2005). Laliberte, Fennell, and Papandonatos (2005) found that patients receiving treatment in facilities participating in cancer research networks were more likely to receive treatment consistent with breast cancer treatment guidelines. A more recent study of the National Cancer Institute's Community Clinical Oncology Program (CCOP) demonstrates that organizations affiliated with the CCOP network were more likely to deliver innovative treatments to patients with early stage breast cancer than non-CCOP programs (Carpenter et al., 2011).

Our prior research on the NIDA CTN has also demonstrated the benefits of research network membership on the adoption of specific medications within SUD treatment organizations. For example, a study by Abraham and colleagues (2010) found that programs that were members of the CTN were more likely than non-CTN programs to adopt both tablet naltrexone and acamprosate for the treatment of alcohol use disorders.

In addition to the general impact of network membership on innovation adoption, it is also important to examine the potential organizational benefits of actual participation in research. Greater involvement in the CTN's research protocols should amplify the value of network membership, because serving as a research site brings greater access to resources, such as technical assistance, training, and financial benefits. To date, two of our prior studies have examined the impact of participation in buprenorphine protocols on the adoption of this specific medication (Ducharme et al., 2007; Knudsen et al., 2009). In both studies, we found that CTPs that participated in buprenorphine protocols were significantly more likely to adopt the medication over time compared to programs that did not participate in these protocols. Since not all CTPs take part in protocols, this particular research network presents a unique opportunity to compare CTPs that have been involved in a greater number of protocols relative to those CTPs with lesser involvement.

The current study moves beyond the examination of a single EBP and instead considers whether greater protocol participation is tied to overall quality using an aggregate measure based on NIDA's model of treatment services (NIDA, 2009). Notably, NIDA's model includes not only evidence-based treatment practices (e.g., motivational interviewing, pharmacotherapy) but also comprehensive "wraparound" services, standardized assessment, and aftercare, which research has demonstrated to be associated with more desirable treatment outcomes.

Consistent with the research network literature and building on our prior work, the objective of this study is to examine the impact of participation in CTN protocols on overall quality of SUD treatment within the CTN's community-based treatment programs. Our hypothesis is that greater participation in protocols is positively associated with overall quality of SUD treatment services available within CTN treatment programs.

2. Methods

Data for this analysis are taken from a study that investigates the organizational structure and impact of the CTN. A key research question of this study is whether protocol

participation is associated with the overall goal of the CTN-- improving the overall quality of SUD treatment. Data were collected via face-to-face interviews with program administrators of 198 community-based SUD treatment programs (CTPs) that represented the current membership of the CTN in 2008–2009. Because of multiple funding cycles since 1999, membership of specific nodes and CTPs has changed over time (Roman, Abraham, Rothrauff, & Knudsen, 2010). In general, university-based nodes invite CTPs to join their nodes at the time of grant submission, but may adjust node membership in response to the needs of specific protocols. These changes have resulted in CTPs having variable amounts of experience in protocol participation.

A CTPs is defined as an organizational unit with an autonomous administrator who holds discretionary control over the unit's budget, thus allowing for instances of multiple CTPs embedded within one larger treatment organization. For example, a set of CTPs located throughout a state may be owned and operated by the same umbrella organization. To be eligible, CTPs were required to offer substance use disorder (SUD) services at least equivalent to American Society on Addiction Medicine (ASAM) level-1 outpatient services (Mee-Lee, Gartner, Miller, Shulman, & Wilford, 1996) or be licensed as opioid treatment programs (OTPs). Units solely focused on assessment or community outreach were not eligible for the study.

A total of 198 CTPs participated in this wave of data collection, representing 83 unique treatment organizations (response rate= 84.7%). Given the distinct treatment practices of OTPs (e.g., less focus on delivery of behavioral therapies, more narrow patient population served, more limited range of services offered), they were excluded from the analyses, resulting in a final sample of 156 programs. Participating treatment programs received a donation of \$150. All research procedures were approved by the University of Georgia's and University of Kentucky's Institutional Review Boards.

2.1. Measures

2.1.1. Dependent variable—To measure overall treatment quality, we created a comprehensive index of treatment services based on NIDA's Principles of Drug Addiction Treatment (2009) that is similar to prior research (Ducharme, Mello, Roman, Knudsen, & Johnson, 2007). This measure includes the self-reported availability of 15 core and wraparound services as well as current use of 20 EBPs. Core and wraparound services included: standardized assessment using the Addiction Severity Index; offering 12-step groups onsite; offering aftercare; offering an HIV/AIDS specific treatment track; linking patients with legal, financial, employment, medical, education, housing, childcare, transportation, family counseling, and domestic violence services either by offering these services onsite, referring patients to another unit within the organization, or providing services via formal contract with an external organization; and providing integrated treatment for co-occurring mental health disorders. Programs reported if they currently offered the following EBPs: motivational enhancement therapy, brief strategic family therapy, contingency management, cognitive behavioral therapy, methadone, oral naltrexone, injectable naltrexone, buprenorphine, acamprosate, disulfiram, bupropion, varenicline, nicotine patch, nicotine gum, SSRIs, HIV testing, Hepatitis C testing, telephone follow-up services, vocational services, and trauma services for women. Each of the 35 items were measured as separate dichotomous variables (1= available/any use, 0 = not available/no use) and then summed to create an overall treatment quality index (range 0 to 35). While we are not suggesting that the goal of a treatment program is to provide all 35 services, the provision of a greater number of services is a proxy for higher quality treatment.

2.1.2. Independent variable: Protocol involvement—At the end of the data collection period for this study (2008–2009), the CTN had completed 21 clinical protocols (excluding survey-based protocols; see Tai et al. 2010 for a detailed description). Program administrators were asked to identify the specific protocols in which their CTP participated. Responses were cross-checked with the CTN’s official list of protocol participants housed in the CTN’s online Dissemination Library (www.disseminationlibrary.org) to confirm that participating CTPs were correctly identified. Note that CTN membership does not guarantee participation in a protocol because there are more members than sites needed to support the CTN’s research agenda. Some CTPs have never been selected to participate in a protocol, either because they are more recent additions to the network or because they have not met criteria for selection.

To measure participation in protocols, we first created a series of dichotomous variables for each of the 21 completed protocols (1=participated in protocol, 0=did not participate) at the time of data collection. These variables were summed to create an index denoting the total number of protocols in which programs participated over the course of their membership in the CTN (possible range of 0 to 21).

2.1.3. Control variables—We included seven additional measures that have been previously shown to be associated with overall treatment quality (Ducharme et al., 2007). Government ownership (1=owned by the government, 0=not owned by the government), location in a hospital setting (1=located in a hospital setting, 0=not located in a hospital setting), and profit status were dichotomous variables (for profit=1, non-profit=0). Program size was measured by the number of full-time equivalent employees (FTEs), with a natural log transformation to adjust for skew. Staff professionalism was measured as the percentage of counselors with a Master’s degree or higher. A dichotomous variable of program accreditation indicated whether programs were accredited by the Joint Commission (JC) or the Commission on Accreditation Rehabilitation Facilities (1=accredited, 0=not accredited). Levels of care differentiated programs that provided outpatient only treatment services (coded ‘1’) from programs that provided inpatient only or mixed levels of care (coded ‘0’). Finally, we included a dummy variable to determine the length of time programs had been members of the CTN because CTPs with a longer history in the CTN have had more opportunities to participate in protocols. CTPs that were members of the CTN at the baseline of our study (2002–2004) were coded ‘1’, CTPs that became members after 2002–2004 were coded ‘0’ on this variable.

2.2. Analytic Strategy

Descriptive statistics were calculated for all variables. Negative binomial regression was used to examine the relationship between research participation and overall treatment quality (i.e., the number of comprehensive services and EPBs adopted), a count dependent variable. Negative binomial regression is appropriate when using a count dependent variable that is overdispersed, and it avoids several violations of assumptions within ordinary least squares (OLS) regression (Long & Freese, 2006). To account for similarities in treatment programs that were part of the same larger treatment organization, we used the “cluster” command in Stata 12.0. This command produces robust standard errors to account for multiple CTPs nested within a single organization. Multiple imputation procedures were employed (Allison, 2002; Royston, 2005a, 2005b; StataCorp, 2011) to address missing data for the percentage of Master’s level or higher counselors (n= 153) and program size (n=150). Ten data sets were imputed.

3. Results

Descriptive statistics are presented in Table 1. Programs provided an average of 13.2 treatment services (range 3 to 26). Participation in protocols ranged from 0 to 7, with CTPs participating in an average of one protocol during their tenure in the CTN. Approximately half of CTPs reported no protocol participation during their membership in the CTN. Few programs were government owned or based in hospital settings. About half of programs provided only outpatient treatment services. The average CTP employed about 26 FTEs. Approximately 61% of programs were accredited and on average, about 46% of counselors held a Master's degree or higher. Roughly one-third of CTPs were members of the CTN at baseline in 2002–2004 and the remaining 69% became members between 2004 and 2008.

Prior to estimating our model of treatment quality, we compared CTPs that participated in at least one protocol ($n=78$) to programs with no protocol involvement ($n=78$) on organizational characteristics using chi-square tests and t-tests corresponding with the level of measurement of the variables. We were interested in whether protocol participation may be a proxy for other organizational characteristics that might ultimately be correlated with treatment quality. However, there were no significant differences between these two groups of CTPs in terms of organizational structure, indicating that CTPs that participated in at least one protocol were very similar to programs with no protocol experience.

3.1. Results of negative binomial regression

Table 2 presents the results of a negative binomial regression model examining overall treatment quality. As hypothesized, greater participation in protocols was positively associated with overall treatment quality. A one-unit increase in protocol participation was associated with a 5.4% increase in the expected number of comprehensive services/EBPs offered. While this association is modest, the differences become more substantial when the range of protocol participation is considered. For example, CTPs that reported the greatest protocol participation (i.e., 7 protocols) had a level of treatment quality that was 44.9% greater [$44.9 = (100)(e^{(.053)(7)} - 1)$] than those programs that had participated in no protocols.

In addition to protocol participation, several organizational characteristics were associated with this index of treatment quality. For-profit programs offered fewer treatment services compared to non-profit programs; the expected number of treatment services offered was 21.9% lower in for-profit programs. Program size was also positively associated with treatment quality. Programs with a more professional workforce offered a greater number of treatment services; a one standard deviation unit increase in the percentage of Master's level counselors ($SD=36.11$) was associated with a 12.0% increase in expected number of treatment services offered. Time was positively associated with overall treatment quality indicating that programs participating in the CTN since baseline offered a greater number of treatment services; the expected number of treatment services offered was 16.3% greater for programs that were members of the CTN at baseline compared to those that joined the CTN after 2002–2004.

4. Discussion

This study examined the association between participation in clinical protocols and overall treatment quality among programs participating in the NIDA CTN, a practice-based research network established in 1999. While prior research has examined the relationship between protocol participation and adoption of single EBPs (e.g., buprenorphine, contingency management), no studies have examined whether greater participation in clinical protocols, the cornerstone activity of PBRNs, is associated with the availability of higher quality treatment. By doing so this study moves beyond examining the relationships between

specific protocols and innovation adoption to address one of the CTN's larger goals, namely improving the quality of SUD treatment.

Negative binomial regression showed support for our hypothesis that greater participation in protocols would be positively associated with overall quality of SUD treatment. This finding supports the idea that involvement in research may amplify the value of PBRN membership not just by facilitating adoption of EBPs that are the foci of protocols, but by improving the overall quality of SUD treatment. While taking into account protocol participation, we also found that time was positively associated with treatment quality, lending further support to the positive impact of CTN participation on overall treatment quality.

Interestingly, we found that organizational characteristics did not differentiate CTPs that had been involved in at least one protocol from those with no protocol participation. Given that CTPs are not randomly assigned to protocols, but rather participate as a result of a structured selection process, we anticipated that organizational structure would be related to protocol participation. To some extent, the lack of differences between CTPs with and without protocol experience reinforces the notion that our measure of protocol participation was not simply a proxy for organizational characteristics that might themselves be associated with treatment quality.

Given that protocol participation was positively associated with quality of treatment, the question remains about how to successfully translate this knowledge and skill base to community-based programs that are not directly involved in clinical research. In fact, the CTN has undertaken a number of dissemination initiatives to meet this objective. For example, in 2001 the NIDA/SAMHSA blending initiative was launched. In collaboration with the Center for Substance Abuse Treatment's Addiction Technology Transfer Center network (ATTC), NIDA and the CTN have developed a series of free blending training packages (e.g., PAMI, MIEDAR) to promote awareness and guide implementation of interventions tested in the CTN. Other blending initiative activities include hosting regional blending conferences and a "training of trainers" (TOT) program in which expert clinicians train other clinicians to supervise and deliver interventions tested in CTN protocols in their home SUD treatment programs (Ling et al., 2010; Martino et al., 2010; Stitzer, Petry, & Pierce, 2010; Tai et al., 2010). The CTN also maintains a web-based dissemination library which provides free access to CTN related presentations and journal articles as well as information on CTN protocols, local and regional training events and other relevant CTN materials (<http://www.disseminationlibrary.org>). While these dissemination activities represent critical efforts to improve the overall quality of SUD treatment in the US, there have been few studies examining the direct impact of these dissemination activities on the quality of treatment services within and outside the CTN.

4.1. Limitations

There are several limitations of the current study. The data are cross-sectional and therefore causal inferences cannot be drawn. Because this is an organizational study, we did not have access to patient-level outcomes and were unable to use clinical outcome data to validate our measure of treatment quality. However, the NIDA publication on treatment services is based on research evidence that such services improve clinical outcomes (NIDA, 2009). An additional limitation is that the quality index measures current use or availability rather than the extent to which these services are implemented. This study cannot address whether these services are reaching all suitable clients or are implemented by all staff. The data does not include treatment programs outside the CTN, therefore we cannot compare the quality of treatment in CTN programs to non-CTN programs. Finally, study findings cannot be generalized beyond the CTN to PBRNs that are focused on other health conditions.

4.2. Conclusions

At their core, PBRNs offer community based clinicians the opportunity to bring innovation to everyday treatment practice and address problems encountered in everyday treatment practice in clinical protocols (i.e., a bottom up approach to clinical research). PBRNs also provide an opportunity to identify barriers to implementation and to tailor implementation strategies to meet the real world needs of community-based treatment programs. In sum, our findings indicate that PBRNs, such as the CTN, may serve as a valuable tool for facilitating the translation of science into everyday practice. However, there are significant strides to be made in disseminating knowledge, skills and training to programs that do not actively participate in clinical research in the wider treatment community. These limitations of current PBRNs can be used to inform the future direction of PBRNs as well as the creation of new PBRNs, e.g., building implementation research into their design.

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Table 1

Descriptive Statistics (N=156)

	Total sample (n=156) % (N) or M (SD)	At least one protocol (n=78) % (N) or M (SD)	No protocols (n=78) % (N) or M (SD)	t-test or χ^2 test
Treatment quality index (0 to 35)	13.17 (5.67)	13.91 (5.55)	12.44 (5.72)	1.634
Protocol participation sum (0 to 21)	0.923 (1.28)	1.85 (1.26)	0	12.945**
Government owned	7.69% (12)	7.69% (6)	7.69% (6)	.000
Hospital based	11.54% (18)	11.54% (9)	11.54% (9)	.000
Program size	2.80 (0.90)	3.85 (0.19)	2.73 (0.95)	.970
% Master's level counselors	45.53 (36.11)	48.35 (36.60)	42.75 (35.63)	.959
Accredited	60.9% (95)	64.1% (50)	57.7% (45)	.673
Outpatient only	50.6% (79)	52.56% (41)	48.72% (38)	.231
CTN member at baseline (2002–2004)	30.8% (48)	20.51% (16)	41.02% (32)	7.704**

^a t-tests and χ^2 tests indicate differences between CTN programs participating in at least one protocol and CTN programs participating in no protocols.

*
p<.05,

**
p<.01.

Table 2

Results of Negative Binomial Regression of Treatment Quality (N=156)

	b (95% CI)	P value
Protocol participation sum	.053 (.013, .093) *	<i>p</i> =.010
Government owned	.073 (-.179, .326)	<i>p</i> =.507
Hospital based	.145 (-.050, .341)	<i>p</i> =.144
For- profit	-.247 (-.493, -.001)	<i>p</i> =.050
Program size	.097 (.011, .183) *	<i>p</i> =.027
% Master's level counselors	.003 (.001, .005) **	<i>p</i> =.003
Accredited	.002 (-.156, .160)	<i>p</i> =.980
Outpatient only	-.089 (-.202, .024)	<i>p</i> =.123
Time	.151 (.005, .296) *	<i>p</i> =.042

Note: b= unstandardized beta; 95% CI=95% confidence interval.

*
p<.05,**
p<.01.