Commitment to Implementation of a Clinical Trial Protocol: Variation by Protocol and Employment Role

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Background

The National Drug Abuse Treatment Clinical Trials Network (CTN) collaborates with community treatment programs to conduct clinical trials testing the effectiveness of emerging pharmacological and behavioral therapies for alcohol and drug use disorders.

Each community treatment program is unique and variation in organizational and workforce characteristics may contribute to variation in patient outcomes. A clinical trial completed within the CTN, for example, found that distance between detoxification and outpatient clinics was the strongest influence on entering outpatient care following detoxification (Campbell et al., 2010).

An interesting and potentially influential workforce characteristic is staff commitment toward implementation of the study intervention. Variation in goal commitment may affect the quality of implementation of a clinical trial intervention and contribute to variation between study sites in patient outcomes. Goal commitment was assessed prior to the implementation of three CTN trials to assess variation between protocols and variation between study sites within protocols.

Methods

The CTN supported the collection of program and workforce characteristics prior to randomizing study participants in three CTN protocols. Program directors and counselors in the 32 sites participating in the three trials completed surveys assessing demographics (e.g., age, gender, education) and attitudes toward the specific study intervention. The Integration Goal Commitment (IGC) Scale (Hollenbeck, Williams, & Klein, 1989) was modified to specify commitment to the implementation of three study interventions: 1) 12-Step Facilitation, 2) medication for smoking cessation, and 3) the web-based Therapeutic Education System.

The IGC is a self-report scale measuring commitment to difficult goals using nine, 5-point (Strongly Disagree to Strongly Agree) items; high scores reflect stronger goal commitment. Goal commitment is calculated by taking the mean response of the scale items. The scale's validity and reliability have been established. In a recent meta-analysis the original authors confirmed the scale's adequate reliability reporting α=0.79 (Klein, Wesson, Hollenbeck, Wright, & DeShon, 2001).

Univariate regression analyses examined associations between descriptive variables and mean goal commitment scores. Variables from the univariate models were included in the multivariate model if they reached the 0.25 significance level. Manual multivariate model building procedures were conducted to find to most parsimonious model of predictor variables associated with goal commitment scores.

Results

Table 1 Demographic and professional characteristics of study participants by protocol.

Characteristic	STAGE-12 (N=119)	S-CAST (N=220)	WEB (N=143)
Female	76.1% (86)	70.0% (154)	79.7% (114)
Non-white	27.7% (33)	28.6% (63)	19.6% (28)
Graduate Degree	24.5% (67)	45.7% (121)	30.1% (81)
In Recovery	44.2% (50)	23.7% (50)	28.7% (41)

STAGE-12: Stimulant Abuser Groups to Engage in 12-Step
S-CAST: Smoking-Cessation and Stimulant Treatment
WEB: Web-delivery of Evidence-Based, Psychosocial Treatment for Substance Abuse

Table 2 Multivariate linear model of goal commitment with predictor variables.

Independent Predictor∞ (N)	Adj. Mean Difference (β)	t-Critical	Adj. R2
Protocol			0.16
S-CAST (220)	-0.47	-6.42*	
WEB (143)	-0.55	-6.98*	
Job Title			
Director (28)	0.51	5.02*	

∞ STAGE-12 (N=119) was used as protocol reference category; Counselor/Supervisor used as job title reference category
* pValue <0.05

Participants:
- Proportions of female and non-white participants were moderately consistent across the three protocols.
- STAGE-12 sites had the lowest proportion of counselors with a graduate degree and the highest proportion of counselors in recovery.

Commitment to Protocol Implementation (Goal Commitment):
- Gender, race, ethnicity, education level (graduate degree) and recovery status did not significantly affect goal commitment scores.
- Protocol type had a significant effect on goal commitment scores.
- S-CAST had an adjusted goal commitment score 0.47 units less than the STAGE-12 adjusted score.
- WEB had an adjusted goal commitment score 0.55 units less than the STAGE-12 adjusted score.
- Job title category also had a significant but positive effect on goal commitment scores.
- Directors reported higher goal commitment then counselors; directors' had a mean goal commitment score 0.51 units higher than the counselors' score.

Figure 1 Mean scores on Protocol Integration Goal Commitment (IGC) scale within protocol and by site.

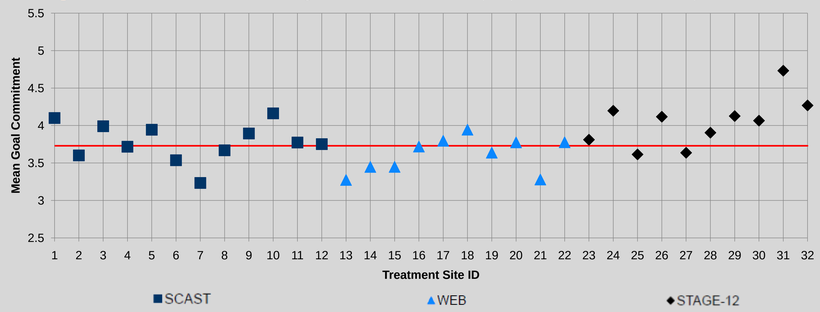

Table 3 Mean goal commitment between protocols.

Study	Goal Commitment Mean ± SD
STAGE-12	4.01 ± 0.61
S-CAST	3.67 ± 0.66
WEB	3.56 ± 0.61

Overall Mean Goal Commitment

CTP Variation in Commitment to Protocol Implementation:
- Sites varied in mean goal commitment scores within each of the three protocols. See Figure 1.
- Figure 2 illustrates the difference between directors' (square) higher mean goal commitment scores when compared to counselors (diamond). Variation in goal commitment scores can be seen within both counselor and director groups.

Figure 2 Mean scores on Protocol Integration Goal Commitment (IGC) scale within protocol, by job title and site.

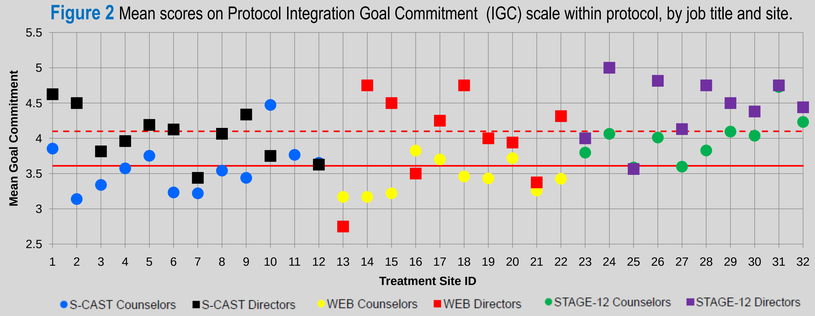

Table 4 Mean goal commitment of job title categories.

Study	Goal Commitment Mean ± SD
Counselor	3.61 ± 0.63
Director	4.10 ± 0.54

Director Overall Mean Goal Commitment
Counselor Overall Mean Goal Commitment

Discussion

This analysis found that both protocol type and job title/job role were associated with variation in goal commitment in three community-based clinical trials.

Protocol Type
- STAGE-12 had the highest goal commitment scores of the three protocols.
- The primary intervention in the STAGE-12 study was integrating 12-step groups into the standard of care practice for stimulant users in the participating CTPs.
- Greater support for the use of 12-Step groups may be a product of clinicians' belief in the effectiveness of this practice.
- Belief in effectiveness may come from clinicians' own use of 12-step in their process of recovery. The STAGE-12 protocol had the highest proportion of counselors in recovery.
- Higher goal commitment to implementing a 12-step group protocol may also reflect the current philosophy of the addiction treatment field.

Employment Role
- After controlling for the effect of protocol type, directors had significantly higher commitment to protocol implementation then counselors.
- The decision to participate in the studies may have been made by treatment center leadership staff and not clinicians which may influence counselor commitment to implementing the protocol.
- Leadership staff may have more positive views of research in general.

Conclusion

Goal Setting Theory (the basis for the IGC scale) hypothesizes that goal commitment contributes to staff performance (Hollenbeck et al, 1989; Locke & Latham, 2002). Variation in goal commitment, therefore, may contribute to the quality of protocol implementation in the three clinical trials. Further analysis is needed to establish a relationship between goal commitment, performance and study outcomes.

References

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