Treatment Integrity and Quality Assurance for Behavioral Interventions

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What is Treatment Integrity?

- Definition
- Components
  - Adherence
  - Competence
- A general research design issue – assuring that research is implemented as planned
- Increased need to answer this question when writing grant applications:
  - How will you know you are actually conducting the treatment you say you are conducting

The Wrong Answer

- “Trust me, I know what I’m doing”

How Treatment Integrity Helps – Internal Validity*

- "Were the study treatments implemented according to manual guidelines?
- Were the treatments evaluated discriminable from each other?
- To what extent did the treatments overlap (e.g. was there contamination of the independent variable)?
- How much variation was there in treatment delivery across therapists (or sites)?
- Did the delivery of the treatment change across time (e.g. did the treatment 'weaken' as it was delivered over the course of treatment?) or throughout the course of the study (e.g. did the therapists 'drift' as they delivered the treatment to a number of patients)?"

Quoted from: Carroll, K. M., Nich, C., Sifry, R. L., Nuro, K. F., Frankforter, T. L., Ball, S. A., Fenton, L., & Rounsaville, B. J. (2000). A general system for evaluating therapist adherence and competence in psychotherapy research in the addictions. *Drug and Alcohol Dependence 57*, 225–238.

How Treatment Integrity Helps – Treatment Process*

- “Were particular interventions associated with good (or poor) outcome?
- Did the therapists vary in their delivery of a treatment to different types of patients (e.g. did more severe patients receive different types of interventions than less severe ones)?
- Is treatment ‘purity’ (e.g. delivering only interventions as defined in the manual) associated with better outcomes than more eclectic approaches?”

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Getting Ready for Treatment Integrity

- Specify the elements of the treatment – define the active ingredients
- Develop manuals to guide the treatment
- Train and certify therapists
  - skillfulness
  - adherence to the manual
  - empathy
  - therapeutic alliance
- Develop coder rating forms and procedures
- Train the raters

Developing Your Treatment

- Manualize your intervention
  - When to write the manual
  - Manual flexibility
- Manual development as an iterative process with different goals/purposes depending on phase of research*

*Table on next slide drawn from: Carroll, K. M. & Rounsaville, B. J. (2000). Efficacy and effectiveness in development treatment manuals. In: A. M. Nezu & C. M. Nezu (Eds.), *Evidence-based outcome research. A practical guide to conducting randomized controlled trials for psychosocial interventions* (pps. 220-243). New York: Oxford University Press.

Manuals and Stage of Treatment Research Studies

"PRINCIPAL ROLES OF TREATMENT MANUAL"	STAGE I	STAGE II	STAGE III
Theoretical "active ingredients"	X	X	X
Treatment techniques, goals, format	X	X	X
Standards for therapist training & supervision		X	X
Unique vs. common elements		X	X
Discrimination from comparison/control		X	X
Discrimination from other approaches to treatment of the disorder		X	X
Evaluation of treatment process		X	X
Guidelines for use with diverse patient groups; in diverse settings			X
Guidelines for tailoring to different patient subgroups			X
Limits of treatment's effectiveness			X

Now that you Have a Manual - Methods for Conducting Treatment Integrity Check

- Clinician self report (not recommended)
- Client report
- Raters differentiating treatments by viewing tapes and sorting (was it this treatment or that?)
- Checklists for content components
- *Behavioral observational coding systems*
- Supervision by experts

Steps in Developing a Coding System

- Generate items
- Developing rating format
  - quantity/adherence
  - quality/skillfulness
- Develop raters' manual
- Select raters – need experience in the treatments to rate
- Train the raters
  - Didactic
  - Group rating of tapes
  - Practice tapes (5-10) with ratings reviewed by "expert"
  - Certify raters

Implementation – Train Your Therapists

- Selection
- Training
  - Reading
  - Didactic
  - Role plays
  - Practice clients
- Certification

Implementation

- Start your clinical trial
- On-going supervision and monitoring of therapists
- Start your treatment integrity ratings
- Periodic meetings and reliability checks for raters
- Use of ratings of monitor therapists

Implementation – Maintaining Treatment Adherence

- Drift from manual adherence
  - Ongoing supervision and observation
  - Regular meetings
  - Corrective feedback

Implementation – Therapist Problems

- What happens when interventionists don’t measure up and don’t improve?
- Red-lining
  - Specific procedures for removing therapists and allowing them back

Implementation – Client Safety

- Client safety measures for BEHAVIORAL interventions
  - I don’t want to do that
  - That makes me want to drink (gamble, have unsafe sex, slap my child, kill myself)
  - I want a different therapist
  - Forget it, I’m not coming to treatment
  - Whoops, I drank and I’m in jail – can you talk to the judge?

Coding Systems for Motivational Interviewing*

- Motivational Interviewing Skills Code (MISC)
- Motivational Interviewing Treatment Integrity Code (MITI)
- Therapist, client global ratings and behavior counts

*Available at the CASAA website

Sample from the MITI

This scale is intended to measure the extent to which the clinician conveys an understanding that motivation for change, and the ability to move toward that change, reside mostly within the client and therefore focuses efforts to elicit and expand it within the therapeutic interaction.

Evocation		1 Low 2 3 4 5 High	

Evocation				
Low			High	
1	2	3	4	5
Clinician actively provides reasons for change, or education about change, in the absence of exploring client's knowledge, efforts or motivation.	Clinician relies on education and information giving at the expense of exploring client's personal motivations and ideas.	Clinician shows no particular interest in, or awareness of, client's own reasons for change and how change should occur. May provide information or education without tailoring to client circumstances.	Clinician is accepting of client's own reasons for change and ideas about how change should happen when they are offered in interaction. Does not attempt to educate or direct if client resists.	Clinician works proactively to evoke client's own reasons for change and ideas about how change should happen.

Sample from Couples CBT

1.a. ASSESSMENT OF CLIENT'S DRINKING: To what extent did the therapist assess the client's drinking since the last session, including the pattern of alcohol use (if any), or the extent and pattern of the client's cravings or urges, by reviewing and graphing the client's self -monitoring cards for the week?

1-----------------2-----------------3-----------------4------------------5 6

not at all a little somewhat considerably extensively N/A

1.b. Rate the quality of the delivery of this component as specified in the manual:

1-----------------2-----------------3-----------------4------------------5 6

very poor poor adequate good excellent N/A

19.a. COUPLE THERAPY III: To what extent did the therapist encourage the spouse to take an active and effective role in supporting abstinence efforts of the woman?

1-----------------2-----------------3-----------------4------------------5 6

not at all a little somewhat considerably extensively N/A

19.b. Rate the quality of the delivery of this component as specified in the manual (across all sessions of the couples manual):

1-----------------2-----------------3-----------------4------------------5 6

very poor poor adequate good excellent N/A

Some Useful References

Barber, J. P., Sharpless, B. A., Klostermann, S. & McCarthy, K. S. (2007). Assessing intervention competence and its relation to therapy outcome: A selected review derived from the outcome literature. *Professional Psychology: Research and Practice, 38*, 493–500.

Carroll, K. M., Nich, C., Sifry, R. L., Nuro, K. F., Frankforter, T. L., Ball, S. A., Fenton, L., & Rounsaville, B. J. (2000). A general system for evaluating therapist adherence and competence in psychotherapy research in the addictions. *Drug and Alcohol Dependence 57*, 225–238.

Carroll, K. M. & Rounsaville, B. J. (200*0. Efficay and effectiveness in development treatment manuals. In: A. M. Nezu & C. M. Nezu (Eds.), *Evidence-based outcome research. A practical guide to conducting randomized controlled trials for psychosocial interventions* (pps. 220-243). New York: Oxford University Press.

Del Boca, F. K. & Darkes, J. (2007). Enhancing the validity and utility of randomized clinical trials in addictions treatment research: I. Treatment implementation and research design. *Addiction*, 102, 1047–1056