How to Write a Treatment Manual

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Treatment manuals are more popular than ever, and new ones are arising at a rapid pace. The growing impetus of managed care to seek empirically based treatments and new funding initiatives by the National Institutes of Health to spur the development of new treatments have accelerated this process.

The following suggestions on how to write a treatment manual are based on a clinical roundtable presented by Steven Hayes, Edna Foa, Patricia Resick, and myself at the November 1997 AABT convention in Miami, Florida (Najavits, Hayes, Foa, & Resick, 1997).

We thought it might be helpful to describe current issues in writing a treatment manual for people embarking on this path. Each of us has had direct experience developing a treatment manual that has undergone empirical validation. We also tried to keep in mind the needs of the field for substantive contributions to psychotherapy development.

Be Aware of the New "Stage" Model of the National Institute on Health for Psychotherapy Development

The National Institutes of Health (NIH) have begun to delineate the scientific stages of psychotherapy development. For the first time in NIH history, they began in the early 1990s to fund investigators to create new psychotherapies, rather than simply to test existing treatments. Specification of stages are still undergoing revision, but can be described as follows (Onken & Blaine, 1995, 1996):

- Stage 1: to develop the treatment and to pilot test it with a basic design (e.g., pre- to post-testing or a passive control such as treatment-as-usual or historical data).
- Stage 2: to test the treatment against an "active" control condition (e.g., an alternative treatment for the same population).
- Stage 3: to test whether the treatment can be generalized to regular clinical settings (i.e., can it be implemented in the "real world"?).

Note that these stages follow an "FDA model," the model used by the Federal Drug Administration for testing new medications. There is debate over whether such stages—and their corollary, medication-model outcome studies—are appropriate for psychotherapies, but this is nonetheless the current reigning model (Hayes, 1998).

Keep in Mind That Developing an Empirically Based Treatment Requires an Enormous Amount of Work

Most people who have undertaken the process are surprised by the huge effort involved. A decade of work is typical. In addition to writing the manual (which will need to undergo substantial revisions as you actually try it out on your population), you will also need the "bells and whistles" of an empirically validated treatment: an adherence scale, therapist training method, a theoretically based rationale to back up your choice of interventions, careful patient selection criteria, the design and implementation of a treatment outcome study to collect data on its impact, and possibly measures specific to your treatment to evaluate it. While these do not all have to be completed in Stage 1, you should be aware of what you are undertaking when you start the process. Also, try to find someone who has developed an empirically based treatment for advice before beginning.

Consider Whether a New Treatment Is Really Needed

We are currently in a "proliferation" phase of new treatments: They are springing up all over, and it is yet to be determined which treatments will stand the test of time. Before embarking on yet another treatment, you may want to consider whether it is really needed: Can the population you are concerned about be treated by an existing manual or some combination of manuals? On the other hand, if you believe a particular population truly needs attention, developing a manual for them can provide a real contribution. For example, the development of manuals for posttraumatic stress disorder, obsessive-compulsive disorder, and substance abuse (to name a few) appears to have helped some patients obtain effective treatment they otherwise would not have received.

Consider the "Ultimate Destination" of Your Treatment at the Beginning

In the NIH stage model described above, it is only at Stage 3 that "generalization" to real-life clinical settings is emphasized. In earlier stages, most investigators seek to create the most ideal conditions possible to test whether the treatment has any chance of working (e.g., the best therapists one can find, substantial training and supervision, providing patients with incentives to stay in the project, etc.) However, to truly provide a treatment that will make a contribution to the field, you may want to keep in mind at the beginning how it might get used later. The chart at the bottom of the page describes this point (see Hayes, Barlow, & Nelson-Grey, in press).

Once you develop a treatment, it will likely be utilized in ways that you never anticipated (e.g., mixed with other treatments, implemented by therapists with less training than you had envisioned, practiced on patients who do not meet the criteria you developed).

Consider Writing a Proposal of Your Treatment and Submitting it to a Book Publisher

Before expending time and resources to develop a new treatment, you may want to submit a proposal of it to a book publisher to see whether they perceive a market for your work. If they agree to contract with you, it is a good sign. If not, you may need to rethink your strategy. Similarly, submitting a grant proposal on your treatment will provide a peer review critique that can help you assess its perceived relevance to the field.

Explore the Diversity of Manuals

All treatment manuals are not created equal. Some are more detailed, some less. Some provide basic training while others assume a particular knowledge base. Look at manuals that exist to get a feel for the kind you might want to develop. Do market research to find out what therapists and patients want in a manual. (For exam-

Research Demands	Practical Demands
Complex (in-depth description)	Simple (can be transmitted easily)
Focused (for a very specific population)	Broad (for a wide array of patients)
Sequenced (highly controlled)	Strategic (apply as needed)
Standardized (tell therapists what to do)	Guidelines (suggest options)

ple, before writing my treatment manual, I conducted a study of 48 cognitive-behavioral therapists at an AABT convention several years ago to obtain their views and preferences on the "ideal manual"; Najavits, Shaw, & Weiss, 1998).

Be Aware That Your Treatment Will Change as You Are Studying It

To be clinically valuable and viable, you will need to keep refining your treatment as you try it out on new patients and new therapists. Thus, while you may design an elegant outcome study with rigor, it will not be the standard psychotherapy trial. You may decide to change the number of sessions, the content of the material, the patient and therapist selection criteria, the training methods—and just about everything else imaginable—as you discover what does and doesn't work. While not a problem per se, it is useful to know this at the start; also, it may have implications for how you interpret your data.

Be Aware That You May Need Pilot Data Before Obtaining Funding

If you choose to obtain funding for the project, you may need to have some basis for others to invest in it, such as pilot data or an initial version of the manual. Investigators have had different paths, with some obtaining a "seed" grant from their university or clinic to start developing the manual; others applying for a small grant from NIH (before applying for a larger grant); and others just sitting down to write without any funding at all. A bootstrap operation with a very barebones approach may be a good way to get your treatment off the ground to develop evidence that it deserves more attention.

Consider the Treatment Modality, Not Just the Treatment Content

In addition to the content of the treatment—which is typically the most interesting part for the treatment developer—there are also important decisions to make about the form of the treatment. Such decisions are a part of the exploration and philosophical soul-searching that helps to refine your conceptualization of what your treatment can give to the field, and how it can have the most impact.

Individual versus group therapy. It could be argued that group treatment is more likely to be widely used, more appealing to managed care, and more affordable for patients. However, group therapy is also harder to study due to cohort effects, dropouts, and the need to amass enough patients to begin a group (during which time your early patients may become better or worse, and may no longer meet criteria for your study). Also, you will need to decide whether to run open or closed groups (in the former, patients can join at any time and still receive the full treatment).

"Stand alone" versus adjunctive treatment. Do you expect your treatment alone to help patients, or will they need other concurrent treatments as well? For example, many substance abuse treatments are designed to be used in conjunction with 12-step drug counseling. Moreover, how will you assess the impact of your treatment relative to other treatments patients are receiving?

Heterogeneity versus homogeneity of patients. How similar do you want patients to be, and on what variables: a particular *Diagnostic and Statistical Manual of Mental Disorders* (*DSM-IV*; American Psychiatric Association, 1994) diagnosis? Demographic characteristics? "Motivation" for treatment?

Therapist characteristics. How will you select therapists?

Consider Whether You Want Your Treatment to Derive From DSM-IV

Many new treatments are defined by one or more diagnoses from *DSM-IV* (First, Spitzer, Gibbon, & Williams, 1997). However, this is not the only approach that may be needed. Is there any other way to define your sample that might be more relevant? The field might benefit from not getting "stuck" just in thinking in terms of the *DSM* system—particularly as many patients who need psychotherapy are not necessarily diagnosable in terms of *DSM* syndromes, but rather suffer from problems that might best be described as functional, existential, life-transition, or system (e.g., family) problems.

Specify Both What to Do and What Not to Do

In describing your treatment, it is helpful to differentiate it from other treatment interventions. Thus, you will want to define both prescribed (what to do) and proscribed (what not to do) interventions.

Have Fun

Despite some of the caveats above, all of us attest to the joy, reward, and creative energy of developing a new treatment that has the potential to help others. If you have read this far, you likely have real motivation to embark on this pursuit. Our final, and perhaps most important conclusion, is that developing a new psychotherapy does indeed provide enormous gratification.

References

American Psychiatric Association. (1994). *Diagnostic and statistical manual of mental disorders* (4th ed.). Washington, DC: Author.

First, M. B., Spitzer, R. L., Gibbon, M., & Williams, J. B. W. (1997). *Structured Clinical Interview for DSM-IV Axis I Disorders, Clinical Version (SCID-CV)*. Washington, DC: American Psychiatric Press.

Hayes, S. C., Barlow, D. H., & Nelson-Grey, R. O. (in press). *The scientist-practitioner: Research and accountability in the age of managed care* (2nd ed.). New York: Allyn and Bacon.

Hayes, S. C. (1998). Market-driven treatment development. *the Behavior Therapist, 21*, 32-33.

Najavits, L. M., Hayes, S., Foa, E., & Resick, P. (November, 1997). *How to write a treatment manual*. Clinical Roundtable presented at the annual meeting of the Association for the Advancement of Behavior Therapy, Miami, FL.

Najavits, L. M., Shaw, S. R., & Weiss, R. D. (1998). *Psychotherapists' views of treatment manuals*. Manuscript submitted for publication.

Onken, L. S., & Blaine, J. (1995). *National Institute on Drug Abuse Behavioral Therapy Development Program Workshop Summary Report*. Unpublished manuscript.

Onken, L. S., & Blaine, J. (1996). *National Institute on Drug Abuse 1993-1994 Investigators Meeting Report*. Unpublished manuscript.

David Teisler of AABT is thanked for his support of this topic.

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