
Moving From Empirically Supported Treatment Lists to Practice Guidelines in Psychotherapy: The Role of the Placebo Concept



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The use of placebos is the “gold standard” in studies of investigational drugs, and of other medical procedures as well. Several recent trends have suggested the use of placebos in studies of psychotherapy to isolate effective treatment components, and as a basis for establishing lists of empirically supported treatments. Unlike within the domain of medicine, in which the logic of placebos is relatively straightforward, the concept of placebo as applied to psychotherapy is fraught with both conceptual and practical problems. The evidence-based practice of psychotherapy can best be promoted through the development of practice guidelines, for which psychotherapy placebos are unnecessary. Moreover, even if problems associated with psychological placebos could be overcome, they are not necessary in psychotherapy research. © 2005 Wiley Periodicals, Inc. *J Clin Psychol* 61: 893–908, 2005.

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The popular conception of the placebo is as a sham or fraudulent treatment—one that works, if at all, solely on the basis of one’s mistaken beliefs in its therapeutic powers. Placebo effects, then, represent the factors (e.g., expectancy for improvement) that are related to any benefits observed in the context of a theoretically inert treatment. Not

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surprisingly, the notion of placebos has acquired negative connotations. These may relate to the history of the concept. The term *placebo* derives from a Latin phrase which translates to "I shall please" (Walach, 2003). As noted by Brown (1998), it is the first word of the vespers for the dead, which were commonly referred to as placebos in the 12th century. By the 13th century, the word had acquired pejorative connotations due to disdain for professional mourners. When adopted by the field of medicine in the 19th century, placebos were originally thought of as substances given to placate patients rather than to heal them. When double-blind controlled trials were introduced to evaluate experimental medications in the early 20th century, a subtle shift in meaning occurred, as placebos became inert substances designed to separate out the "real" biochemical effects of drugs from those produced by mere psychological factors (Leber, 2000). The idea of the "placebo control condition" was born. Such control conditions were designed to distinguish biologically mediated effects from any effects due to extraneous factors. Current discussions of the placebo concept often refer to both meanings, i.e., placebos as treatments or treatment components, and placebo controls as specific conditions in experimental trials of treatments.

In terms of placebos as treatments, over the past few decades there has been a gradual appreciation that placebos are anything but inert. In a classic article, Beecher (1955) estimated that placebos benefit between 30–40% of patients with a variety of medical conditions. Since that time, medical placebos have been found to have wide-ranging effects, including benefits in the treatment of asthma, pain, postoperative wounds, the common cold, headache, nausea, anxiety, etc. (Shapiro & Shapiro 1997). Although some have recently questioned the robustness of placebo effects (Hróbjartsson & Gøtzsche, 2001), the weight of the evidence strongly supports the powerful clinical benefits of placebo treatments for a wide range of conditions (Kirsch, 2002; Wampold, Minami, Tierney, Baskin, & Bhati, this issue). Indeed, a growing body of literature attests to the powerful effects of placebos in both drug and even surgical interventions (Benedetti et al., 2003; Mayberg et al., 2002; McRae et al., 2004; Moseley et al., 2002).

Application of the Placebo Concept to Psychotherapy

As control conditions in experimental trials, the use of placebos historically has been the domain of medicine. Over the past four decades, however, increasing attempts have been made to employ placebo control conditions in evaluations of psychotherapy. We propose that two broad factors have encouraged the application of placebo controls to psychotherapy research: (a) the apparent logic of using placebo conditions to control for threats to internal validity (i.e., the observed improvement related to factors other than the treatment itself); and (b) the desire to emulate the "gold standards" of medical research to promote psychotherapy as a legitimate treatment, and in turn, to promote the professional practice of psychotherapy. As a detailed analysis of the historical and sociological factors behind the professional promotion of psychotherapy is beyond the scope of this article, we instead focus on the logic of placebo controls in psychotherapy research.

Several recent trends have led psychotherapy researchers to attempt to borrow the logic of medical research to provide better experimental tests of psychotherapy efficacy. The first development is the increasing recognition of the powerful role of factors such as expectancies and the therapeutic relationship in psychotherapy (Frank, 1961; Shapiro, 1971). Since psychological factors are precisely those for which pill-placebos are designed to control in drug trials, it is natural to contemplate extending the idea of placebos to psychotherapy studies. The general idea is that a psychological placebo could control for factors thought to be incidental to the theoretically important factors responsible for treatment effects in the same

way that pill-placebos control for incidental psychological factors in drug trials. In other words, a psychotherapy placebo would control for all therapeutic factors (e.g., expectancy, therapeutic relationship, hope, treatment credibility) minus the techniques or processes (e.g., exposure to feared stimuli, transference work) theorized to produce the specific treatment benefits of the experimental psychotherapy.

The second factor contributing to the increased interest in placebo controls in psychotherapy is the growing number of randomized controlled trials (RCTs) directly comparing medications and psychotherapy, both as monotherapies and more recently as combined treatments. Such studies typically adopt the logic and procedures of standard placebo-controlled drug trials, including a pill-placebo condition. In an effort to provide balance to the study design, researchers sometimes attempt to design placebo psychotherapies to parallel pill-placebos. For example, Heimberg et al. (1998) attempted to design an educational–supportive group treatment in a RCT for social anxiety disorder that would have comparable credibility to cognitive-behavior group therapy but not any of the theorized “active” ingredients of the treatment.

A third and closely related development is the use of psychotherapy for conditions that traditionally have been treated with drugs, and vice versa. For example, cognitive-behavior therapy (CBT) is increasingly used to treat conditions traditionally reserved for pharmacotherapy, such as panic disorder (White & Barlow, 2002) and even schizophrenia (Rector & Beck, 2001; Gaudiano, in press), whereas medications are increasingly applied to conditions traditionally considered the unique domain of psychotherapy, such as posttraumatic stress disorder (Stein, Zungu-Dirwayi, van der Linden, & Seedat, 2004).

Finally, as elaborated further below, recent efforts to establish criteria for defining empirically supported psychotherapies have attempted to emulate the model of the U.S. Food and Drug Administration (FDA) for approving medications. Since the FDA criteria require drugs to demonstrate superiority to a pill-placebo, one could argue that no less should be required of a psychotherapy, which raises the question of how best to design appropriate psychotherapy placebo conditions.

Problems With the Placebo Concept in Psychotherapy

At first glance, the idea of psychological placebo conditions in psychotherapy outcome studies holds intuitive appeal. Upon further consideration, however, it quickly becomes clear that the notion is fraught with difficulties due to: (a) the practical problems with the placebo concept even in medicine, (b) the numerous practical and theoretical problems encountered when attempting to apply the concept to psychotherapy specifically, and (c) the potential ethical issues involved with the use inclusion of placebos. First, placebos are most easily applied to biological treatments but even in medicine, things are not always so clear-cut. For example, consider clinical depression, which is notoriously responsive to pill-placebos. Several reviews have concluded that most of the effects of antidepressant medications are replicated by pill-placebos (Fisher & Greenberg, 1989; Gaudiano & Herbert, in press; Kirsch & Sapirstein, 1998). Moreover, it is possible that the relatively modest incremental effects of antidepressants over pill-placebos reflect further placebo effects due to the frequent problems with unblinding in antidepressant drug trials. Unblinding occurs when patients, their physicians, or both become aware of a treatment condition in an RCT due to side effects (or lack thereof). Patients who are aware that they are taking a biochemically active drug may have higher expectations for improvement or increased motivation due to psychological processes such as effort justification, cognitive dissonance, or behavioral activation, requiring the use of so-called “active” placebos that also produce side effects similar to the antidepressants.

Despite practical difficulties, the theoretical justification for placebos in medicine remains relatively straightforward. However, theoretical problems are compounded even further when researchers attempt to apply the placebo concept to psychotherapy trials. In medicine, placebos are used to distinguish psychological effects from biochemical ones. In psychotherapy, however, all effects are necessarily “psychological” in nature. Psychological placebos therefore cannot distinguish two qualitatively distinct classes of causal variables as in medicine, but are limited to distinguishing among types of psychological effects. As discussed below, this raises the difficult question of which psychological factors are to be considered bone fide or “real” and which are relegated to “placebos” (Kirsch, this issue).

Aside from conceptual problems, there are seemingly insurmountable practical problems with the idea of a psychotherapy placebo. Foremost among these is the fact that unlike drug trials, traditional psychotherapy cannot be delivered blindly.¹ In a double-blind drug trial both patient and clinician are kept blind to whether the patient is receiving an active drug or a placebo (notwithstanding the problems with unblinding discussed above). In psychotherapy studies, the therapist by definition knows what treatment is being delivered, and would generally know if it was considered a placebo condition. This raises difficult problems of therapist bias and expectancy effects, called *allegiance effects* (Luborsky et al., 1999). Similarly, research has demonstrated that it is difficult to engender comparable expectations for improvement among patients for placebo psychotherapies and the treatments against which they are being compared (Borkovec & Nau, 1972; O’Leary & Borkovec, 1978).

Finally, as placebo conditions are intended to be inert and therefore not to produce their effects directly as a result of the treatment, some argue that it is ethically unsound to include such conditions when participants have diagnosable and impairing problems (O’Leary & Borkovec, 1978; Noble, Gelfand, & DeRubeis, this issue). These researchers argue that alternative designs, such as those that use comparison treatment groups or that limit the number of participants who are exposed to potentially inferior placebo conditions, are more ethically appropriate.

Proposed Placebo Controls in Psychotherapy

Despite these problems, the idea of a placebo psychotherapy condition is appealing, and so scholars have proposed a variety of ways of defining such conditions. Unfortunately, each of these apparent solutions raises more problems that it solves.

¹The so-called *power* or *energy therapies* may be the exceptions to the rule that double-blind trials cannot be conducted in psychotherapy. For example, thought field therapy (TFT; Callahan & Trubo, 2001) is a novel therapy that proposes that disturbances in the body’s invisible “energy meridians” result in psychological distress and can be corrected by tapping on meridian-corresponding body points (Gaudio & Herbert, 2000). An outcome study of TFT could easily be designed so that both therapist and patient are blind to the “correct” body-tapping sequences hypothesized to be responsible for clinical benefits. In fact, because the energy therapies make such specific and potentially falsifiable claims regarding the putative mechanism of action in their treatments, a trial using any lesser methodology than a single- or double-blind trial is largely uninformative. Recently, Wells and colleagues (2003) published a randomized trial comparing a TFT derivative, called *emotional freedom techniques* (EFT; Craig, 1999), to diaphragmatic breathing in the treatment of specific animal phobias and found EFT to be superior. However, a subsequently published trial by independent investigators found no difference in outcome when EFT-specific and placebo-tapping sequences were used to treat public speaking fears (Waite & Holder, 2003). Furthermore, a recent single-blind trial of TFT using random-tapping sequences found similar null results (Pignotti, 2004). It is important to note, however, that the treatment components in these therapies for which the placebo concept is meaningful are not psychotherapeutic per se, but rather involve direct physical manipulations (e.g., tapping on various parts of the patient’s body).

Some theorists have defined placebo psychotherapies as those limited to “nonspecific” factors (Lohr, DeMaio, & McGlynn, 2003; Shapiro, 1971). The idea is that nonspecific factors comprise those that are not unique to any given intervention, but that occur across a wide range of treatments. A closely related concept is “common factors” (Critelli & Neumann, 1984), which are defined as those “not specific to any particular technique” (Lambert, this issue, p. 856). Both of these approaches beg the question of how unique a factor must be before it moves from the realm of specific to nonspecific or common. Must the factor be completely unique to a given treatment to be considered specific? If so, then no matter how seemingly novel, it would cease to be specific if incorporated into a single other treatment program. On the other hand, if a factor can be shared by several treatments but still be considered specific, then how commonly used must it become before moving from the domain of specific to nonspecific or common? Consider, for example, exposure to anxiety-provoking stimuli as an intervention for anxiety disorders. Although behavior therapists consider exposure to be specific to behavioral interventions due to its theoretical importance and to the specific procedures developed for its application, other psychotherapy theorists classify exposure as nonspecific based on the rationale that most treatments involve discussion of (and therefore some degree of exposure to) anxiety-relevant stimuli (Lambert, this issue). Likewise, person-centered therapists would likely consider unconditional positive regard or accurate empathy specific to their approach, whereas many others would classify these as nonspecific. Thus, the distinction between specific and nonspecific becomes solely a function of one’s perspective.

A way to resolve the apparent arbitrariness of the boundary between specific and nonspecific is to rely on theory. Building on the classic work of Grünbaum (1985, 1986) and Brody (1985), Lohr and colleagues (Lohr et al., 2003; Lohr, Olatunji, Parker, & DeMaio, this issue) have proposed a detailed analysis of the constituents of psychotherapy effects. The central thrust of their analysis is that specific factors are those that are highlighted by the theory upon which one’s psychotherapy is based; all other factors fall into one of several nonspecific or incidental categories. Placebo factors would therefore include those not specified as theoretically important by the psychotherapist’s theory. A positive feature of this approach is the emphasis on linking technical developments to theory, an issue that has arguably received insufficient attention over the past couple of decades. However, it does not solve the problem of distinguishing specific from nonspecific factors. The central problem is that the distinction depends solely on one’s particular theory, so that clinicians of differing theoretical persuasions examining an identical treatment program would each highlight different factors as specific. In other words, theoretically specific factors to one theorist would be placebo factors to another. As there exists no widely accepted unified theory of psychotherapy (and likely never will be), the factors that comprise a placebo psychotherapy therefore would depend entirely upon one’s theory, and would vary considerably. Moreover, as theories evolve over time, the demarcation between placebo and nonplacebo factors would likewise change. Once again, the contrast with pill-placebos in medicine is clear. Right or wrong, medicine is united in embracing a biochemical metatheory of illness, and pill-placebos are designed to distinguish effects due to these biochemical factors from those due to psychological factors. Moreover, medical researchers need not agree on the specific biochemical mechanisms theorized to be important in any given case to agree on the demarcation between biochemical and psychological factors. Thus, relying on theory to define psychological placebos does not solve the problem of the arbitrariness of distinctions between placebo and theoretically active treatment components in psychotherapy.

Alternatively, Steward-Williams and Podd (2004) recently argued that placebos can be defined as substances or procedures that have no “inherent powers” to produce an

effect; whatever effects are produced are therefore due solely to the recipient's beliefs in the treatment. According to this view, "a psychotherapy placebo is simply a psychological procedure that has no inherent power to produce an effect . . . it works only because a person believes it will" (p. 325). This definition echoes Paul's (1966) classic definition of placebo psychotherapy as an intervention that works only by virtue of one's belief that it will work. The problem is that this definition begs the question of how to distinguish "inherent powers" of psychotherapy from those related to the patient's beliefs. Although one can experimentally manipulate expectancies (see Southworth & Kirsch, 1988, for an interesting example), it is difficult to imagine how one would design a psychotherapy that did not influence patient beliefs. In addition, as noted by Kirsch (2004, 2005, this issue), to the extent that psychotherapy actively attempts to change patient beliefs and expectancies, it could be considered either an active treatment or a placebo according to this definition.

In summary, the various proposals to define placebo psychotherapies are all characterized by thorny conceptual and practical problems. The analogy with medical placebos simply does not comport readily to the realm of psychotherapy. This conclusion raises intriguing questions. First, if we reject the idea of psychotherapy placebos, what standard do we use to define psychotherapies as empirically supported? Second, without psychotherapy placebos, how should psychotherapy research proceed?

Placebos and Empirically Supported Treatments

In 1993, the Division of Clinical Psychology of the American Psychological Association (APA) launched an effort to define empirically supported treatments (ESTs) to promote scientifically based practice. The task force, now known as the Committee on Science and Practice (CSP), issued their first report in 1995 (Task Force, 1995), with subsequent updates in 1996 and 1998 (Chambless et al., 1996, 1998). Among the products of the CSP's work were decision rules for defining ESTs, and lists of psychotherapies that met these criteria. The fundamental purpose of establishing lists of ESTs was not a scientific one per se, but rather a public policy one. That is, lists of ESTs ultimately were intended to promote the evidence-based practice of psychotherapy. The CSP's efforts occur in the context of a growing movement over the past decade toward the practice of medicine based upon the best available scientific evidence. For example, The Cochrane Review (www.cochrane.org) publishes evidence-based reviews of medical and psychiatric treatments by independent experts, which are regularly updated as new research is published. In the United Kingdom, the National Institute of Clinical Excellence (www.nice.org.uk) publishes practice guidelines in medicine and psychiatry. The practice of psychotherapy, especially in the United States, however, has lagged behind this trend. Recent surveys of clinicians show that many do not base their treatment decisions on the state-of-the-art in clinical research (Addis & Krasnow, 2000; Freiheit, Vye, Swan, & Cady, 2004). Establishing a list of ESTs has been viewed as an important and necessary step in promoting evidence-based practice in the arena of psychotherapy.

Despite good intentions, the effort to identify ESTs has proven quite contentious. On the one hand, many psychotherapists are opposed to the idea of the specification of ESTs in principle, viewing such efforts as dangerous to a model of psychotherapy based more on art than science, and resting on an epistemology based more on clinical intuition than empiricism. Many of these clinicians question the usefulness of the application of scientific methods in general, and RCTs in particular in guiding the practice of psychotherapy, and bemoan the apparent loss of clinician autonomy that the EST movement would appear to entail (Levant, 2004).

Although advocating the advantages of a scientific perspective on psychotherapy, many scientifically minded clinicians and scholars also have found problems with the effort to list ESTs. Scientist–practitioners tend not to object to efforts to promote empirically supported practice in principle, but have been quite critical of the specific criteria by which ESTs have been defined by the CSP. Herbert (2000, 2003) outlined several problems, foremost of which is the inadequacy of wait-list control (WLC) conditions as baselines for conferring EST status. That is, since most psychotherapies can be shown to be statistically superior to no treatment, simple comparisons to a no-treatment or WLC condition, although important scientifically as a tool to partial the sources of variance in psychotherapy effects, are of little practical value in defining ESTs.²

For most psychological disorders, saying that a treatment works better than no treatment is saying little more than the treatment has been studied. Herbert (2002, 2003) identified other problems with the EST criteria established by the CSP, including the absence of criteria for distinguishing among treatments or treatment procedures, the absence of mechanisms for identifying harmful treatments or for removing treatments from the list, and the insufficient attention given to the methodological quality of studies that are to count as evidence for ESTs. Furthermore, Rosen and Davison (2003) have proposed that efforts should be made to identify empirically supported principles of change, rather than trademarked therapies. Although this proposal highlights the important link between theory and practice, it does not solve most of the problems associated with listing ESTs. That is, lists of empirically supported principles of change face many of the same conceptual and practical problems as lists of ESTs (Herbert, 2003).

At first glance, one solution to the problem of the inadequacy of the WLC as a baseline for ESTs is the psychotherapy placebo. In fact, the EST criteria for a “well-established treatment” requires at least two trials where the experimental treatment is “superior (statistically significantly so) to psychological or pill placebo or to another treatment” (Chambless et al., 1998, p. 4). Using psychotherapy placebos as the standard for defining ESTs has the advantage of consistency with medication trials, in which experimental drugs must outperform pill-placebos to be considered indicated for a given condition. Moreover, such a strategy brings us full circle to Paul’s (1966) promotion of psychotherapy placebos more than three decades ago.

As we have seen, however, the notion of placebo psychotherapy is fraught with so many problems as to be conceptually and practically meaningless in this context. So, if no treatment (or a WLC) is an insufficient baseline for defining ESTs, and if placebo psychotherapy will not work, might there be another condition that could suffice as an adequate baseline? Unfortunately, any alternative also is associated with insoluble problems. One might propose that to be considered an EST a treatment must outperform a standard baseline, such as supportive psychotherapy. Supportive psychotherapy need not be considered a placebo in the sense that it need not be conceptualized as a sham or inert treatment, but instead would be considered a legitimate intervention. A supportive psychotherapy condition could consist of ingredients that are commonly employed across a wide range of psychotherapies, including rapport with a knowledgeable professional, a

² A very important use of WLC and no-treatment conditions is identifying harmful or iatrogenic effects. Although most psychotherapies have been found not to be harmful, there are a few notable exceptions, such as certain debriefing programs for the sequelae of acute trauma (Van Emmerik, Kamphuis, Hulsbosch, & Emmelkamp, 2002), group therapy for adolescent conduct problems (Dishion, McCord, & Poulin, 1999), and recovered memory therapy for dissociative identity disorder (Lilienfeld et al., 1999) (see Bootzin & Bailey, this issue for a review). Unfortunately, most discussions of ESTs, including the criteria developed by the CSP, do not discuss WLC control conditions in this context, but instead focus on their use as a standard for identifying positive treatment effects.

hope-inspiring rationale, active listening and support, and basic education about the target problem. Supportive psychotherapy in this context might appear to be analogous to a pill-placebo in a medication trial, in that it would control for expectations for improvement and important factors such as the therapeutic relationship with a professional in the same way that a pill-placebo would control for similar factors in a drug trial.

Although well-designed supportive psychotherapy conditions can provide useful controls in some psychotherapy studies (e.g., Heimberg et al., 1998, Tarrier et al., 1998), several problems emerge when considering them as universal baselines for defining ESTs. First, it is impossible to design a supportive psychotherapy that would be sufficiently consistent across populations to be considered the same treatment. A supportive psychotherapy for schizophrenia would look quite different from a supportive psychotherapy for a specific phobia. Without such consistency, however, the baseline would shift for each disorder, making it impossible to employ a unified standard for defining ESTs. This is not a problem for medication trials, as any differences in pill-placebos across disorders are trivial. Furthermore, supportive psychotherapy conditions will make it difficult or even impossible to achieve comparable expectations for improvement across treatments, despite the fact that controlling for such expectancies is in fact one of the principle reasons for using the condition in the first place. Problems with allegiance effects, in which treatments tend to perform better in trials conducted by investigators with an allegiance to the treatment (Luborsky et al., 1999), would likely be compounded in the case of comparing an experimental treatment to supportive psychotherapy for many disorders. Finally, a supportive psychotherapy condition designed as a control condition in clinical trials would likely lack external validity, as it likely would not correspond to typical treatment in the community.

An alternative might be to use nonspecific or common factors treatments as baselines for defining ESTs. This option is equally problematic, however. As discussed above, attempts to define a treatment as nonspecific or common raise fundamental definitional questions. Moreover, each of the problems discussed above with regard to supportive psychotherapy also arises with nonspecific or common factors treatments.

A third option would be to require psychotherapies to outperform pill-placebos in order to be declared ESTs (Klein, 1997). This solution has the advantage of a single comparison condition against which to evaluate both psychotherapies and drugs. Unfortunately, the use of pill-placebos to control for expectancy effects in psychotherapy commits a critical category error. That is, patients' expectations associated with a pill-placebo could be quite different from their expectations associated with psychotherapy. Therefore, pill-placebos cannot serve as a universal baseline for evaluating psychotherapies as ESTs.

In summary, there is no viable, standardized, and universal baseline condition for defining psychotherapies as empirically supported. Using no treatment or WLC conditions sets the bar so low as to be essentially meaningless, whereas placebo psychotherapy, supportive psychotherapy, nonspecific treatment, common factors treatment, and pill-placebo are each fraught with either conceptual problems, practical difficulties, or both. Shifting the focus from constructing lists of ESTs to empirically supported treatment principles does not help us escape this quandary, as we are still left with the problem of specifying a workable universal baseline condition, among other difficulties. Without a viable baseline, the effort to construct meaningful lists of empirically supported psychotherapies (or psychotherapy procedures) is doomed to ultimate failure.

From Empirically Supported Treatments to Psychotherapy Practice Guidelines

The insurmountable obstacles to defining ESTs do not mean that we must abandon the goal of evidence-based treatment and retreat to a prescientific practice of psychotherapy.

Recall that the idea of constructing lists of ESTs was promoted not as an end in and of itself, but as a means of furthering the science-inspired practice of psychotherapy. In fact, it was anticipated that any preliminary efforts to define empirically supported treatments would necessarily change over time in response to the evolution of our knowledge and understanding of psychotherapy based on the state-of-the-art research in the field. Our thesis is that evidence-based practice can be promoted best through the development and dissemination of practice guidelines, and that constructing lists of ESTs is unnecessary to that process.

A practice guideline is essentially a blueprint for treating a particular condition. Ideally, practice guidelines specify an algorithm of decision rules based on the best available scientific data. Such guidelines avoid or minimize most of the problems associated with lists of ESTs. For example, there is no need for a universal baseline condition to define efficacy across disorders. Instead, one simply uses the best available evidence for each disorder or treatment target. For some problems, available data may be limited to WLC conditions, whereas in other cases sophisticated comparison and component control studies may have isolated effective treatment components. In either case, the guidelines would reflect the best available evidence at the time, no matter how well developed. This fact highlights another important property of practice guidelines: Like the scientific data on which they are based, they are always viewed as works in progress, subject to regular updating as new evidence emerges. This updating could include replacing one treatment with another in the decision hierarchy if the latter is shown to be more effective or efficient, or trimming unnecessary components from a multicomponent treatment program based on the results of dismantling studies. In this case, practice guidelines would be fully compatible with the notion of identifying empirically supported treatment procedures (Rosen & Davison, 2003), including relationship factors (Lambert, this issue).

In the context of practice guidelines, no single research design reigns supreme. In terms of experimental trials, a variety of control conditions has their place, depending on the specific question being addressed and the state-of-the-art in a given area. Comparisons against a WLC provide the initial test of a treatment's efficacy by documenting safety. Although obviously limited in the information they can convey, in the absence of other data such trials provide the preliminary basis for initial practice guidelines. If a treatment is shown to be more effective than a WLC for a given disorder, and in the absence of additional data, that treatment would be preferred as the first choice over another treatment without even such a rudimentary level of empirical support. In addition, comparative trials permit the evaluation of a treatment against various alternatives, including other psychotherapies as well as drug therapies or the combination of the two. In other words, practice guidelines can easily accommodate treatments that cross modalities based on the results of comparative trials (e.g., studies comparing psychotherapy to medications). Finally, various component control studies permit the refinement of practice guidelines to highlight the specific procedures and factors responsible for treatment effects, while eliminating those that are superfluous (Borkovec & Sibrava, this issue; Lohr et al., this issue). Regardless of control conditions, all outcome trials have the potential of evaluating potential predictors of treatment outcome, thereby contributing to the goal of developing decision rules based on pretreatment patient characteristics to maximize the likelihood of positive outcomes for individual patients.

Despite the importance of RCTs in determining the relative magnitude of the effects of alternative treatments and in isolating specific treatment components, the data that contribute to practice guidelines need not be limited to experimental trials. Some of the potentially most powerful mediators of psychotherapy effects (e.g., strength of the therapeutic alliance, patient personality) may be best studied through quasi-experimental or correla-

tional procedures. Practice guidelines are not bound to a single, one-size-fits-all threshold to determine a treatment's empirical legitimacy. Rather, any relevant, methodologically sound data can be used to build or extend the guidelines for a particular treatment target.

Establishing and maintaining practice guidelines will not be without significant challenges. First, clinicians who resisted the effort to identify ESTs will likely be even less sanguine about practice guidelines, which will likely be viewed as eroding their professional autonomy. Guidelines may be especially threatening for clinicians who practice forms of psychotherapy that either have not been subjected to empirical evaluation or that have not fared especially well in such evaluations relative to alternative procedures. Although such professional issues are important to address in the context of the dissemination of practice guidelines, they are not reasons to abandon or even slow down the effort. Second, practice guidelines have the potential to be sabotaged by political considerations. For example, the American Psychiatric Association (APA, 2004) has begun developing practice guidelines for some of the major psychiatric conditions. These guidelines, however, tend to be skewed in favor of drug treatments, even in cases in which specific psychotherapies work better in the long term, such as in depression (Young, Weinberger, & Beck, 2001). Therefore, the dispute over practice guidelines likely will continue to highlight fundamental philosophical disagreements over the nature of psychotherapy. Although both sides provide compelling arguments for or against evidence-based practice, the field ultimately must make a choice that is most consistent with current professional and societal standards, while continuing to discuss and debate the issue internally. For the foreseeable future, science is likely to remain the preferred epistemological approach for evaluating treatments in the health professions, psychotherapy included. Other countries and U.S. organizations such as the American Psychiatric Association already have begun to develop preliminary practice guidelines. If the field of clinical psychology remains in the wings as others move to the forefront of this pursuit, the profession's ability to influence the scientific practice of psychotherapy will be in jeopardy.

Ensuring that practice guidelines are based on state-of-the-art science can be fostered in several ways. First, review committees should consist of knowledgeable scientists from a variety of disciplines (e.g., psychology, psychiatry), representing a variety of theoretical backgrounds. Second, the explicit guiding principle should be examination of all methodologically sound data, which should always trump disciplinary guild considerations. This would include incorporation of other potentially useful sources of evidence not fully appreciated in existing criteria for defining EST, including the clinical significance of treatment effects (Jacobson & Truax, 1991), the real-world applicability and effectiveness of treatments from RCTs (Clark, 1995), the cost effectiveness (Lave, Frank, Schulberg, & Kamlet, 1998), and moderators and mediators of treatment effects (Kendall, Holmbeck, & Verduin, 2004). Of equal importance is the need to demonstrate that such guidelines actually improve patient outcome. For example, emerging evidence suggests that algorithm-based guidelines may improve outcome in biological treatments for depression (Trivedi et al., 2004). Along these lines, the committee should be required to cite the evidence used to construct each aspect of the guidelines. The review process should be completely open and transparent, with ample opportunity for input and feedback from interested stakeholders.

Viable Psychotherapy Research Designs

Useful practice guidelines depend upon scientifically sound research. If we dismiss the placebo psychotherapy condition as a viable comparator, how then are we to proceed? In a world of limited resources, it is crucial to consider how best to invest available resources

in the effort to develop, evaluate, refine, and disseminate effective and scientifically sound psychotherapies.

Psychotherapy theorists tend to fall roughly into two broad camps: Those who conclude that most psychotherapies are essentially equivalent in efficacy (Lambert, this issue; Wampold, 2001; Wampold et al., this issue), and those who believe that certain therapies are demonstrably superior to others when considered in the context of specific disorders (Hunsley & DiGiulio, 2002; Lohr et al., this issue). In theorizing about the specific factors responsible for therapeutic effects, the former group tends to focus on relationship factors and patient expectancies, whereas the latter tends to focus on procedural techniques. In either case, research designs are needed to refine our understanding of specific factors—whether they are process variables, techniques, or their combination—that are responsible for therapeutic effects.

Borkovec and colleagues (Borkovec & Castonguay, 1998; Borkovec & Sibrava, this issue) propose that only component control experimental designs can isolate such specific cause–effect relationships in psychotherapy. In fact, Borkovec and Sibrava go so far as to advocate that comparative outcome trials, in which different psychotherapy programs are contrasted, be abandoned as scientifically uninformative. It is certainly the case that component control studies provide the best means of discovering specific cause–effect relationships (e.g., Herbert et al., in press). But does it follow that WLC or comparative designs do not have a place? In fact, WLC conditions are indispensable, at least in the early stages of investigating a therapy program or procedure to establish safety. Such conditions afford the first level of control for a variety of factors that may be associated with improvement, such as spontaneous remission, maturation effects, regression to the mean, and the effects of repeated assessments. It makes little sense to initiate component control studies of a treatment until it demonstrates superior efficacy relative to WLC.

Likewise, comparative trials are critical for several reasons, although their necessity comes more from a public policy perspective than a purely scientific one. First, they permit an assessment of the relative effectiveness of existing treatment programs, either alone or in combination, thereby prioritizing targets for further research. It makes the most sense to focus the considerable resources necessary to conduct component control studies on the treatments that are the most effective for a given disorder. Second, comparative trials permit the assessment of the effects of a novel treatment relative to an established norm. Again, one must first demonstrate that a novel treatment is at least as effective as an established one before questions of the mechanisms responsible for its effect become compelling from a resource allocation perspective. In both of these cases, comparative studies suggest the most fruitful targets for subsequent component-control studies.

Comparative trials have the potential to be of enormous practical importance by examining the relative efficacy of widely practiced treatments. For example, by far the most common treatment for major depressive disorder is antidepressant medication (Stafford, MacDonald, & Finkelstein, 2001). Since CBT also has been shown to be an effective treatment for depression, it becomes important to determine how the two approaches compare. In fact, several studies have found roughly comparable results between antidepressant drugs and CBT at post treatment, with superiority for CBT after discontinuation, and enhanced efficacy achieved by combining both (see Hollon, Haman, & Brown, 2002 for a review). If comparative designs were abandoned, we would have no tools for investigating crossmodality treatments other than examination of effect sizes across studies, which is of limited value due to the inability to control for study specific characteristics. In the case of depression, there would be little basis for arguing that CBT

should be considered an alternative to antidepressant medication, or even as the first-line treatment for depression. Thus, WLC, comparative outcome, and component control designs all have important roles to play in the quest to develop and evaluate effective psychotherapies. Placebo psychotherapies, however defined, are not necessary to this project.

Finally, the use of experimental and data analytic procedures for systematically investigating potential moderators (i.e., the conditions under which a treatment is effective) and mediators (i.e., the variables that explain the process through which treatment is effective) of treatment effects is essential to the development of scientifically valid psychotherapies and of guidelines for their use. Relevant and robust factors such as the therapeutic alliance, expectancy for improvement, and treatment credibility are often neglected in RCTs. However, modifications can be made to the design of RCTs so that these variables can be investigated in concert with treatment efficacy. These investigations require specific methodological adjustments, such as the assessment of mechanism/process variables during treatment delivery and the use of regression techniques for separating variance in outcome (Kendall et al., 2004; Kraemer, Wilson, Fairburn, & Agras, 2002). Moreover, quasi-experimental and single-subject designs can also yield important information about such factors that can then be incorporated into practice guidelines.

Summary and Conclusions

The development of effective psychotherapies, including the identification of the specific factors responsible for therapeutic effects and the underlying theoretical mechanisms that explain those factors, is important for both scientific and practical reasons. Recent trends, including the increase in crossmodality research involving comparative trials of psychotropic medications and psychotherapy, as well as the project to identify empirically supported treatments, highlight psychotherapy placebos as possible experimental tools. Psychotherapies are inherently complex and multifaceted, and a control condition that would permit an elegant separation of theoretically important from inert factors would be of considerable value. The notion of a psychotherapy placebo, analogous to a pill-placebo in medicine, has intuitive appeal. However, the concept of placebo makes little sense when applied to psychotherapy. Consideration of the problems with the notion of psychotherapy placebo sheds light on the best strategies for promoting evidence-based practice, and for research strategies aimed at furthering the development of empirically supported psychotherapies. Although the development of psychotherapy practice guidelines will inevitably face much of the same opposition as earlier attempts to construct lists of ESTs, such a step is necessary to continue to advance the research and dissemination of effective psychosocial interventions to consumers.

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