

## **EVIDENCE-BASED TREATMENTS FOR CHILDREN AND ADOLESCENTS WITH PHOBIC AND ANXIETY DISORDERS: ISSUES AND COMMENTARY**

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### **Abstract**

The movement to develop evidence-based assessment and treatment is of relatively recent origin; nonetheless, it has quickly revolutionized the field of mental health. This development has however been highly controversial and has served to divide the mental health professions. Three major issues associated with evidence-based treatment are examined: (a) some treatments have been shown to be more effective than others and, as a result, the "Dodo Bird" effect (i.e., all treatments are equivalent) is no longer tenable, (b) use of treatment manuals might lead to mechanical, inflexible interventions that result in loss of creativity and innovation in the therapy enterprise, and (c) treatments shown to be effective in clinical research settings might not be applicable or transport to "real-life" clinical practice settings. These issues are addressed and areas of rapprochement are explored. These are exciting times for the field of child and adolescent psychotherapy, and the various articles in this special issue attest to what we know and what we have yet to learn in treating anxiety disorders in youth.

*KEY WORDS: treatment outcome, phobic and anxiety disorders, child and adolescent, manualized treatment, evidence-based practice.*

### **Resumen**

El movimiento para el desarrollo de instrumentos de evaluación y procedimientos de tratamiento basados en la evidencia es relativamente nuevo; no obstante, ha revolucionado rápidamente el campo de la salud mental. Este desarrollo no ha estado exento de controversias e incluso ha dividido a profesionales de la salud mental. En el presente artículo se han examinado tres planteamientos asociados con los tratamientos basados en la evidencia: (a) algunos tratamientos han demostrado ser más eficaces que otros, lo que desmiente el efecto del "pájaro

dodo" (*Dodo Bird*) (es decir, todos los tratamientos son equivalentes), (b) la idea de que el uso de manuales de tratamiento pudiera llevar a intervenciones mecánicas e inflexibles que dieran lugar a la pérdida de creatividad e innovación en el proceso terapéutico, y (c) que los tratamientos que han mostrado su eficacia en contextos de investigación clínica pueden no ser aplicables o transferidos a contextos de la práctica clínica en la "vida real". En este artículo, se abordan estas cuestiones y se exploran áreas cercanas. Estos son tiempos emocionantes en el campo de la psicoterapia para niños y adolescentes, y los trabajos que aparecen en este monográfico constituyen una muestra de lo que conocemos y de lo que aún tenemos que aprender acerca de cómo tratar los trastornos de ansiedad en niños y adolescentes.

PALABRAS CLAVE: *resultados del tratamiento, trastornos de ansiedad, niños y adolescentes, manuales de tratamiento, práctica basada en la evidencia.*

### Evidence-based treatments

Although the movement to develop evidence-based assessment and treatment has revolutionized the field of mental health, this development is of relatively recent origin (Chambless & Ollendick, 2001). In order to appreciate the issues associated with this movement, it is important to consider some of the early findings and controversies associated with psychotherapy research. In his now in (famous) review of the effects of adult psychotherapy, Eysenck (1952) boldly asserted that psychotherapy practices utilized in the 1950s were no more effective than the simple passage of time (i.e., spontaneous remission). Levitt (1957, 1963) subsequently reviewed the child psychotherapy literature and put forth a similar conclusion. Although these reviews were unsettling for clinicians and researchers alike, they served as a wake up call to the mental health professions (Kazdin, 2000). Since the time of these reviews, advances in the study of developmental psychopathology, as well as developments in assessment and treatment research and practices, have resulted in well over 1500 psychotherapy studies in the child mental health arena (Durlak, Wells, Cotton, & Johnson, 1995; Kazdin, 2000; Ollendick, King, & Chorpita, 2006) and four major meta-analyses examining the effects of child psychotherapy (Casey & Berman, 1985; Kazdin, Bass, Ayers, & Rodgers, 1990; Weisz, Weiss, Alicke, & Klotz, 1987; Weisz, Weiss, Han, Granger, & Morton, 1995). These meta-analyses have provided strong empirical evidence that child and adolescent psychotherapy works (Weersing & Weisz, 2002). More specifically, systematic reviews of the literature now illustrate that therapy for children and adolescents outperforms wait-list and attention-placebo conditions. In addition, it is becoming abundantly clear that some forms of psychotherapy work better than others, a finding that has allowed the fields of clinical child psychology and child psychiatry to move beyond the question of whether psychotherapy works for children and adolescents to identifying the efficacy of *specific* treatments for children who present with *specific* behavioral, emotional, and social problems. These are exciting times for the field of child and adolescent psychotherapy, and the various articles in this special issue attest to what we know and what we have yet to learn in treating the phobic and anxiety disorders in youth.

The present paper examines past efforts to identify evidence-based psychosocial treatments for children and adolescents and raises a series of critical issues relevant to this movement. First, it should be noted that this movement is embedded within a larger movement known as “evidence-based medicine” or “evidence-based practice” (Sackett, Richardson, Rosenberg, & Haynes, 1997, 2000). Evidence-based practice at its core is an approach to knowledge and a strategy for improving performance outcomes (Ollendick & King, 2004; Ollendick et al., 2006). Although it is not wedded to any one theoretical position, it does require treatments to be based on scientifically-credible evidence that is obtained largely through randomized clinical trials (RCTs). In a RCT, children with a specific presenting problem are randomly assigned to a treatment condition or a control condition, such as a wait-list or attention-placebo condition, and the effects of these conditions are compared. Although there are limitations to such a design (Westen, Novotny, & Thompson-Brenner, 2004), it appears to be the best strategy for rigorously examining the efficacy of treatment (i.e., controlling for extraneous variables through randomization) and ruling out biases and expectations (on the part of the child, the child’s parents, and the therapist) that can result in misleading findings. Although the RCT is the gold standard for evaluating treatment conditions, information or opinions obtained from observational studies, logical intuition, personal experiences, and the testimony of experts can also serve as evidence for treatment efficacy. Although such evidence is valuable, it represents a less credible and acceptable form of evidence from a scientific standpoint (i.e., it occupies a lower rung on the ladder of evidentiary support). At the same time, it is these initial clinical observations and “clinical hunches” that frequently lead to the development of new and innovative treatments that can be subsequently evaluated in RCTs.

Although the approach to develop, identify, disseminate, and use evidence-based psychosocial treatments (initially referred to as “empirically validated” or “empirically supported,” see Chambless, 1996; Chambless & Hollon, 1998) seems scientifically laudable (if not necessary), this movement has been highly controversial, at least in the field of mental health. On the surface, it seemed unlikely that some would object to the initial report developed by the Society of Clinical Psychology (Division 12) of the American Psychological Association in 1995 or that the movement associated with it would become so hotly contested. Surely, identifying, developing, and disseminating treatments that “work” and possess empirical support should be encouraged, not discouraged, especially by a profession that is committed to the welfare of those whom it serves.

Unfortunately, this task force report was not only controversial; moreover, and unfortunately, it served to foster a divide within the mental health professions (Ollendick & King, 2000, 2004; Ollendick et al., 2006). In this paper, we present not only the core of this approach but also address some of the myths associated with use of these treatments (i.e., dangers of manualization, loss of therapist creativity). In order to create a more unified field, we believe it is important for advocates of empirically-supported treatments to not only communicate the approach to others but also to address the concerns of those who oppose this movement. In the first part of this paper, we will define evidence-based treatments. We then

subsequently illustrate and discuss some of the contentious issues associated with the development, use, and promulgation of these treatments. Finally, we conclude our discourse by offering recommendations for future research and practice with a particular focus on evidence-based treatments for phobic and anxiety disorders in youth. Other papers in this special issue will provide a more in-depth review on the efficacy of specific treatments for specific phobic and anxiety disorders.

### Defining evidence-based treatments

Although the movement to evaluate the efficacy of psychosocial treatments surely occurred prior to 1995, the first formal report to address the evidence-based practice movement was issued at that time. This report on what was then referred to as empirically-validated treatments, issued by the Society of Clinical Psychology Task Force on Promotion and Dissemination of Psychological Procedures, was developed by clinicians and researchers from a number of theoretical orientations, including psychodynamic, interpersonal, cognitive-behavioral, and systemic points of view. This diversity in membership was crucial in identifying and promulgating *all* psychotherapies of proven worth, not just those emanating from a specific school of thought. This diversity was valuable in generating alternative ways of thinking about effective treatments, but it also made defining empirically-validated treatments a difficult task. As may be evident, no treatment is ever fully validated as there are always important questions to ask about any treatment (e.g., the essential components of treatments, client characteristics that predict or moderate treatment outcome, and the mechanisms or mediators that account for behavior change).

According to the 1995 report, three categories were established for "empirically-validated" treatments: (1) *well-established treatments*, (2) *probably efficacious treatments*, and (3) *experimental treatments* (Table 1). The primary distinction between *well-established* and *probably efficacious* treatments is that a well-established treatment must prove to be superior to a psychological placebo, pill, or another treatment whereas a probably efficacious treatment must prove to be superior only to a wait-list or no treatment control condition. Secondly, well-established treatments require evidence from at least two different investigatory teams whereas the effects of a probably efficacious treatment only require evidence from one investigatory team. Furthermore, client characteristics should be well-specified (e.g., age, sex, ethnicity, diagnosis), and the clinical trials should be conducted with treatment manuals for both types of evidentiary support. Finally, outcomes associated with treatment should be demonstrated in "good" group design studies or a series of well-controlled single-case design studies. "Good" designs were those in which it was reasonable to conclude that the benefits observed were due to the effects of treatment and not due to chance or confounding factors such as the passage of time, the effects of psychological assessment, or the presence of different types of clients in the various treatment conditions (Chambless & Hollon, 1998; also see Kazdin, 1998, and Kendall, Flannery-Schroeder, & Ford, 1999 for a fuller discussion of research design issues). *Experimental* treatments, on the other

hand, are those treatments not yet shown to be at least probably efficacious. This category was intended to capture treatments frequently used in clinical practice but not yet fully evaluated or newly developed ones not yet put to the test of scientific scrutiny. It should be noted that the development of new treatments was strongly encouraged in the report. In addition, treatments can “move” from one category to another dependent on the empirical support available for that treatment over time. For example, an experimental treatment might move into probably efficacious or well-established status after further scientific evaluation. The categorical system was intended to be a dynamic one, so that new and innovative treatments could build evidentiary support over time.

**Table 1**  
Criteria for empirically validated treatments

<p><i>I. Well-established treatments</i></p> <p>A. At least two good between-group design experiments demonstrating efficacy in one or more of the following ways:</p> <ol style="list-style-type: none"> <li>1. superior to pill or psychological placebo or to another treatment</li> <li>2. equivalent to an already established treatment in experiments with adequate statistical power (about 30 per group)</li> </ol> <p>OR</p> <p>B. A large series of single case design experiments (<math>n &gt; 9</math>) demonstrating efficacy. These experiments must have:</p> <ol style="list-style-type: none"> <li>1. used good experimental designs, and</li> <li>2. compared the intervention to another treatment in A.1.</li> </ol> <p>Further criteria for both A and B:</p> <ol style="list-style-type: none"> <li>C. Experiments must be conducted with treatment manuals.</li> <li>D. Characteristics of the client samples must be clearly specified.</li> <li>E. Effects must have been demonstrated by at least two different investigators or investigatory teams.</li> </ol> <p><i>II. Probably efficacious treatments</i></p> <p>A. Two experiments showing the treatment is more effective than a waiting-list control group</p> <p>OR</p> <p>B. One or more experiments meeting the well-established treatment criteria A, C, D, but not E</p> <p>C. A small series of single case design experiments (<math>n &gt; 3</math>) otherwise meeting well-established treatment criteria B, C, and D.</p>
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### **Evidence-based treatments: issues of concern**

In an earlier paper, Ollendick (1999) identified three major concerns associated with the evidence-based treatment movement: (a) some treatments have been shown to be more effective than others and, as a result, the “Dodo Bird” effect (i.e., all treatments are equivalent) was no longer tenable and some practices

might possess more evidentiary support than others, (b) use of treatment manuals might lead to mechanical, inflexible interventions that result in loss of creativity and innovation in the therapy process, and (c) treatments shown to be effective in clinical research settings might not be transportable to "real-life" clinical practice settings. These concerns are reasonable ones and we hope to address them in order to determine if they compromise the evidence-based treatment movement.

*Differential effectiveness of psychosocial treatments.* In our earlier and more recent reviews of the literature (Ollendick & King, 1998, 2000, 2004; Ollendick et al., 2006), we have reported a rather alarming set of findings. Namely, many of the treatments currently in use in clinical practice have not been systematically evaluated (with the exception of behavioral and cognitive-behavioral treatments) and therefore do not qualify as well-established or even probably efficacious treatments. For example, across problem areas such as depression, phobias, anxiety, ADHD, oppositional behaviors, and conduct problems, *no* randomized controlled trials using "good" experimental designs have been identified for psychodynamic psychotherapies or family systems therapies (with the exception of oppositional behavior wherein psychodynamic and family systems interventions have been shown to be *less* efficacious than behavioral based ones; see Brestan & Eyberg, 1998). In addition, interpersonal psychotherapy (Mufson et al., 1994; Mufson, Weissman, Moreau, & Garfinkel, 1999; Rosello & Bernal, 1999) has only been established as efficacious in the treatment of depression in adolescents, but not for other disorders in adolescence or for any disorders in childhood. Given that many of these treatments have not been evaluated, we simply do not know whether they are effective.

Although a number of treatments have not been evaluated, there is considerable evidence for the efficacy of behavioral and cognitive-behavioral treatment procedures in the treatment of different child psychopathologies. These treatments have not only been found to be effective, but they have also been found to fare better than other interventions in meta-analytic studies (see Weisz et al., 1987, 1995, for reviews which indicate the superiority of behavioral over "non-behavioral" treatments). Although these findings are exciting for advocates of behavioral and cognitive-behavioral therapies, the results are less exciting for practitioners of other forms of psychotherapy. Moreover, behavioral and cognitive-behavioral therapists should proceed with some caution, since there is a limited evidentiary base for the efficacy of even these treatments. For example, in the child and adolescent area, we have been able to identify only one well-established treatment for the anxiety disorders (cognitive behavior therapy), two well-established treatments for specific phobias (participant modeling, reinforced practice), two well-established treatments for ADHD (behavioral parent training, operant classroom management), and two well-established treatments for oppositional and conduct problems (Patterson's social learning parent training program, Webster-Stratton's videotape modeling parent training).

Although the evidence is limited, these treatments serve as a good start in establishing evidence-based practice. It is clear that additional treatments will need

to be developed and evaluated, but how should clinical practice proceed until that time? What is the current status of 'treatment as usual' in clinical practice settings and should such treatments continue to be used until more empirical support is available? These questions are crucial if we are to move into an age of accountability associated with evidence-based practice. Weisz, Huey, and Weersing (1998) examined these questions in a re-analysis of their 1995 meta-analytic study. They selected treatment studies of clinic-referred children who were treated in service-oriented clinics or clinical agencies by practicing clinicians. Over a period 50 years, nine studies were identified that compared "treatment as usual" to a control condition in a clinical setting. Effect sizes associated with these nine studies ranged from  $-.40$  to  $+.29$ , with a mean effect size of  $.01$ , an effect size well below the average effect size ( $+.70$ ) obtained in their meta-analyses of behavioral and cognitive-behavioral treatments. An effect size of  $.01$  indicates that the treated children were no better off than the untreated children following treatment, a finding that is alarming.

Unfortunately, findings regarding treatment as usual are not limited to the clinical studies reviewed by Weisz et al. (1998). Bickman and colleagues have reported similar outcomes in their examination of a comprehensive mental health services program for children in the United States (Bickman, 1996; Bickman et al., 1995). In what became known as the Fort Bragg Project, the United States Army spent over \$80 million to provide an organized continuum of mental health care to children and their families and to test its cost-effectiveness relative to a more conventional and less comprehensive intervention (treatment as usual) in a matched comparison site. The findings showed good evidence for better access to treatment and higher levels of client satisfaction in the experimental site, but the program failed to demonstrate clinical and functional outcomes superior to those in the comparison site. Overall, this study resulted in more interventions at a greater cost, but more positive outcomes were not associated with greater intensity of treatment and costs. Moreover, neither treatment produced gains that approached those found in clinical trials reported by Weisz et al. (1995) in their meta-analytic review. It is clear that expensive and intensive treatments do not always result in greater outcomes.

Furthermore, in a school setting, Weiss, Catron, Harris, and Phung (1999) evaluated the effectiveness of child psychotherapy as typically delivered ("treatment as usual") in that setting using a RCT design. A total of 160 children who presented with problems of anxiety, depression, aggression, and attention were randomly assigned to treatment and control conditions. Children were enrolled in normal elementary and middle schools and their mean age was 10.3 years. Treatment was provided by mental health professionals hired through regular clinic practices (six were masters' level clinicians and one was a doctoral level clinical psychologist). Overall, the therapists reported favoring psychodynamic-humanistic approaches over cognitive and behavioral ones. The treatment itself was open-ended (i.e., not guided by manuals) and delivered over an extended 2-year period on an "as needed" and individualized basis. The results of the trial provided little support for the effectiveness of "treatment as usual" in this setting (overall effect size of  $-.08$ ),

indicating that the treatment was no better than an academic tutoring comparison control condition.

Overall, then, results from these studies and others show the importance of developing, validating, and transporting effective treatments to clinical and school settings. "Treatment as usual" does not appear to be very effective treatment when it is compared to non-therapy alternatives (e.g., tutoring) or to no treatment at all. Interestingly, these results seem to mirror the findings of Levitt (1957, 1963) reported over fifty years ago in which treatment was found to be no more effective than the passage of time. If we are to move into an age of evidence-based practice and bring legitimacy to treatment outcome research, we must take these findings seriously, as they have important implications for the future of child and adolescent mental health treatment.

Finally, we suggest that we must be mindful of the ethics of continuing to provide either ineffective or harmful treatments to children and their families (recall that the effect sizes for the nine clinic-based studies reviewed by Weisz et al., 1995 ranged from  $-.40$  to  $+.29$  and that the effect size reported by Weiss et al. was  $-.08$ ). As psychologists, the identification, promulgation, and use of empirically-supported treatments is consistent with the ethical standard that psychologists "should rely on scientifically and professionally derived knowledge when making scientific or professional judgments" (Canter, Bennett, Jones, & Nagy, 1994, p. 36). Yet, as noted in a lively debate on this issue (Eiffert, Schulte, & Zvolensky, 1998; Persons, 1998; Zvolensky & Eiffert, 1998, 1999), the identification and use of empirically-supported treatments represent a two-edged sword. On the one hand, it might seem unethical to use a treatment that has not been empirically-supported; on the other hand, given that few empirically-supported treatments have been developed, it might be unethical to restrict practice to problem areas and disorders for which treatment efficacy has been established (Ollendick & Davis, 2004). What should a clinician do when children and their families present with problems for which empirically-supported treatments have not yet been developed? Although there is not an obvious answer to this question, we agree with the conclusions reached earlier by Kinscherff (1999) in an article entitled "Empirically supported treatments: What to do until the data arrive (or now that they have)?" Kinscherff suggests that "clinicians should develop a formulation of the case and select the best approaches for helping a client from among the procedures in which the clinician is competent. Clinicians should remain informed about advances in treatment, including empirically-supported treatments, and maintain their own clinical skills by learning new procedures and strengthening their skills in areas in which they are already accomplished. Because there are limitations to how many treatments any one clinician can master, a key professional competence is knowing when to refer for a treatment approach that may be more effective for the client" (p. 4). Overall, this approach emphasizes the importance of knowing one's limitations, the importance of continuing education, and the need to refer when the appropriate treatment is outside of one's competencies.

A final comment should be made about what to do in those instances in which a referral is not possible (e.g., rural settings, few practitioners), or when the evidentiary

support is lacking, Chorpita and his colleagues have proposed an “evidence-based” decision making model, a model that was recently implemented in the Hawaii Child and Adolescent Mental Health Division (Chorpita & Donkervoet, 2005; Daleiden & Chorpita, 2005). Under this model, the therapist is encouraged to use individual case-specific evidence to guide clinical choices that need to be made for treatment. Routine measurement of clinical progress has the potential to provide empirical support for the clinical choices made when evidence from RCTs is not available. This model allows for services to continue in the face of minimal supportive evidence, but requires that clinical and functional improvements are evident *for that individual case*. Only preliminary evaluation of this alternative model is available at this time (Daleiden, 2004), but it appears to offer promise and accountability when it is not possible to use or implement evidence-based treatments.

*Manualization of psychosocial treatments.* The recommendation that well-established and probably efficacious treatments use a treatment manual was identified by Ollendick (1999) as the second major source of controversy in the empirically-supported treatment movement. As noted by Chambless (1996), the inclusion of a treatment manual leads to greater standardization and an operational definition of the treatment. The treatment manual provides a description of the treatment that makes it possible to determine whether the treatment was actually delivered as intended (i.e., the treatment possesses “integrity”). Second, the use of a manual allows other mental health professionals and researchers to be aware of the actual components of the treatment that were supported in the efficacy trial. Manualization of therapy is especially important to clarify the many variants of therapy. For example, given the many types of cognitive-behavior therapy or psychodynamic therapy, it is largely meaningless to claim that a study found that cognitive-behavior therapy or psychodynamic therapy was efficacious. What type of psychodynamic therapy was used in this study? What form of cognitive-behavior therapy was used in that study? As Chambless (1996, p. 6) noted, “brand names are not the critical identifiers. The manuals are.”

In response to this controversy about the use of manuals, Chorpita, Daleiden, and Weisz (2005) proposed an alternative model that emphasizes underlying *principles* of change rather than *procedures* of change. In their critique of procedural manuals, several concerns were raised. First, the requirement that a treatment is defined by the procedures outlined in the manual (and not by the principles underlying the procedures) implies that revisions to a manual require empirical justification to begin afresh every time a manual is changed or altered in some way. For example, although the Coping Cat (Kendall, Kane, Howard, & Sigueland, 1990) has been subjected to several good randomized clinical trials for the treatment of childhood anxiety disorders, the currently available Coping Cat manual (Kendall, 2002) is a revised version of the original manual. Strict adherence to procedural principles would indicate that the latter manual is not empirically supported in its present form, a conclusion which seems counter to common sense and good clinical practice (i.e., treatment manuals change based on experience obtained while using them). Relaxing the strict interpretation of “manualization” might allow for small revisions to benefit from prior empirical support, but, of course, then the issue becomes one

of defining boundaries. How much change is too much? Is the manual basically the same or has it been altered appreciably?

A second concern raised by Chorpita et al. (2005) involves the unavailability of manuals for several problem areas and what to do in these instances. For example, there are currently no empirically-supported treatment manuals for adolescent panic disorder (although a treatment approach based on the work with adults with panic disorder has been proposed and evaluated by Ollendick (1995a), and Mattis and Ollendick (2002), with single-case but not RCT support). Under a strict interpretation of the Division 12 guidelines, any treatment for adolescent panic might be as good as any other one (because none has received strong empirical support). Again, this is a conclusion that would be counter to common sense and good clinical practice, especially so given the strong support for cognitive-behavioral interventions with adults with panic disorder (Barlow, Gorman, Shear, & Woods, 2002) and the promising support for adolescents (Mattis & Ollendick, 2002). Treatments based on the underlying principles of change found in cognitive behavior therapy would seem to be fruitful to apply, and to be evaluated systematically before using other interventions with little or no support.

Finally, Chorpita and colleagues raised the issue of what to do when more than one manual exists for a given disorder and how clinicians should go about selecting one of them for use. For example, for childhood and adolescent depression, there are at least two promising treatment manuals (Kaslow & Thompson, 1998, Seligman et al., 2004), including those based on cognitive-behavioral and interpersonal approaches. How does a therapist determine which one or ones to use? There are few extant guidelines for how one selects one of the available treatments.

As noted, the model proposed to address these concerns involves a methodology for the identification and selection of "common elements" or underlying principles of evidence-based protocols. Chorpita et al. (2005) demonstrated that "practice elements" (e.g., "time out," "exposure," "cognitive restructuring") could be reliably coded and then empirically "factored" into groupings representing particular approaches. Each factor could yield a practice element profile, which would denote the relative frequency of the occurrence of different practice elements for a particular problem. For example, the practice element profile for childhood anxiety showed that exposure was universally present in the evidence-based protocols coded, and other practice elements such as psychoeducation, relaxation, and self-monitoring were highly common, though not universal. Similarly, common elements for the treatment of childhood depression include behavioral activation, cognitive restructuring, and address of interpersonal issues (Seligman, Goza, & Ollendick, 2004). Such a "common elements" approach represents an alternative to the strict definition of manuals at the level of individual "procedural" manuals. As such, the model addresses the concerns reviewed above, in that the similarity of revised manuals can be empirically defined (e.g., the revised Coping Cat would share the support of the original manual), unavailability of manuals can be addressed through the construction of a profile averaging across similar problem areas (e.g., a cognitive-behavioral protocol for childhood anxiety would be recommended for panic disorder), and the presence of more than one manual could be addressed by

creating a master profile, which represents the aggregate frequency of approaches (e.g., a clinician could develop a new approach including the elements outlined in the profile). Although this model offers some promising alternatives, its use as an intervention strategy awaits additional empirical investigation.

The model proposed by Chorpita et al. (2005) arose in the context of considerable controversy regarding the use of "procedural" manuals, as noted above. In recent years, a flood of commentaries – some commendatory, others derogatory – have filled the pages of several major journals, including the *American Psychologist*, *Australian Psychologist*, *Journal of Clinical Psychology*, *Journal of Consulting and Clinical Psychology*, *Clinical Psychology: Science and Practice*, *Clinical Psychology Review*, and *Psychotherapy*. Some authors have viewed manuals as "promoting a cookbook mentality" (Smith, 1995), "paint by numbers" (Silverman, 1996), "more of a straightjacket than a set of guidelines" (Goldfried & Wolfe, 1996), "somewhat analogous to cookie cutters" (Strupp & Anderson, 1997), and a "hangman of life" (Lambert, 1998). Others have viewed them in more positive terms (e.g., Chambless & Hollon, 1998; Craighead & Craighead, 1998; Heimberg, 1998; Kendall, 1998; King & Ollendick, 1998; Ollendick, 1995b, 1999; Strosahl, 1998; Wilson, 1996a, b, 1998). Wilson (1998, p. 363), for example, suggested that "the use of standardized, manual-based treatments in clinical practice represents a new and evolving development with far-reaching implications for the field of psychotherapy."

In its simplest form, a treatment manual can be defined as a set of guidelines that instruct or inform the user as to "how to do" a certain treatment and, ideally, that specify the principles that underlie that treatment (Ollendick, 1999). They both specify and standardize the treatment at the same time. Although some opponents of manual-based treatment support the evidence-based practice movement, they express other concerns, including the notion that treatments evaluated in research settings will not generalize to "real-life" clinical settings or that manual-based treatments will offer little opportunity for flexibility or clinical judgment. Seligman (1995, p. 967), for example, indicated that unlike the manual-based treatment of controlled, laboratory research – in which "a small number of techniques, all within one modality" are delivered in fixed order for a fixed duration – clinical practice is, by necessity, self-correcting. "If one technique is not working, another technique – or even modality – is usually tried." As noted by Wilson (1998), this characterization of manual-based treatment is simply wrong. A variety of treatments have been "manualized," including those embedded in psychodynamic (e.g., Strupp & Binder, 1984), interpersonal (e.g., Klerman, Weissman, Rounsaville, & Chevron, 1984), behavioral (Patterson & Gullion, 1968) and cognitive-behavioral theory (e.g., Beck, Rush, Shaw, & Emery, 1979); moreover, these manuals allow for flexible use and, for the most part, are responsive to progress or regress in treatment.

It should be recalled that the movement to manualize treatment practices existed long before the Task Force issued its report in 1995. Almost 30 years earlier, Patterson and Gullion (1968) published their now-classic book "Living with Children: New Methods for Parents and Teachers," a "how to" parent and teacher that has been the foundation for many behavioral treatment programs of oppositional, defiant, and conduct problem children. Not surprisingly, treatment

based on this “manual” was one of the first treatments designated as “evidence-based.” Once again, prior to the task force report, Luborsky and DuRubeis (1984) commented upon the potential use of treatment manuals in a paper entitled “The use of psychotherapy treatment manuals: A small revolution in psychotherapy research style.” Similarly, Lambert and Ogles (1988) indicated that manuals were not new; rather, they noted, manuals have been used to train therapists and define treatments since the 1960s. It seems to us that the 1995 Task Force Report simply reaffirmed a movement that had been present for some years and that had been adopted by the mental health field for studies designed to explore the efficacy of various psychotherapies.

At the same time, probably the most contentious issue may be that the Task Force Report asserted that psychotherapies described and operationalized by manuals should not only be identified, but they should also be promulgated and disseminated to clinical training programs, practicing mental health professionals, the public, and to third party payors (i.e., insurance companies, health maintenance organizations). Many clinicians were concerned that such actions were premature and that they would prohibit or, in the least, constrain the practice of those psychotherapies that had not yet been manualized or shown to be effective. They also were concerned that the development of new psychotherapies would be limited, if not stifled, by this movement. Although these are possible outcomes of the evidenced-based treatment movement, they need not be inevitable ones. In fact, it seems to us that these developments can serve to stimulate additional treatments by systematically examining the parameters of effective treatments as well as the therapeutic mechanisms of change (see Kendall, 1998, and Wilson, 1998, for examples), a position that we fully support.

What is the current status of this movement toward manualization in the treatment of children and adolescents? First, it should be clear that the studies summarized in our reviews of empirically-supported treatments for children either used manuals or the procedures were described in sufficient detail as to not require manuals (as originally suggested by the Task Force Report [1995] and by Chambless [1996]). As we noted earlier, manuals are simply guidelines that describe treatment procedures and therapeutic strategies, and in some instances, provide an underlying theory of change on which the procedures or techniques are based. Kendall and his colleagues (Kendall, 1998; Kendall & Chu, 2000; Kendall, Chu, Gifford, Hayes, & Nauta, 1998) have addressed misperceptions surrounding use of treatment manuals and have identified six (mis)perceptions that plague manual-based treatments: How flexible are they? Do they replace clinical judgment? Do manuals detract from the creative process of therapy? Does a treatment manual reify therapy in a fixed and stagnant fashion, and thereby stifle improvement and change? Are manual-based treatments effective with patients who present with multiple diagnoses or clinical problems? And, are manuals primarily designed for use in research programs, with little or no use or application in service-providing clinics? Although clear answers to these penetrating questions are not available at this time, careful research is desperately needed to explore these (mis)perceptions. In addition, Kendall and his colleagues provide evidence from their own work with children who have anxiety

disorders that at least some of these issues or questions may be not be problematic. For example, flexibility of treatment implementation is an issue that many critics have raised; accordingly, it should be investigated empirically to determine if the degree to which a manual is implemented flexibly affects treatment outcome.

In a study with anxious children by Kendall and Chu (2000), the degree to which flexibility affected treatment outcome was explored. In their study, Kendall and Chu defined flexibility as a construct that measures the therapist's adaptive stance to the *specific* situation at hand while adhering *generally* to the instructions and suggestions in the manual. Ratings on the degree to which the manual was implemented in a flexible manner were obtained from 18 different therapists who had implemented the Coping Cat cognitive-behavioral, manual-based treatment for anxious children (Kendall, 2002). Flexibility ratings were obtained retrospectively on a 13-item questionnaire, with each item rated on a 1- to 7-point scale as to the extent of flexibility used in implementing treatment (e.g., "The manual suggests that clinicians spend 40-45 minutes of the session teaching the outlined skills to the child and 10-15 minutes of the session playing games. How flexible with this were you?" And, "During therapy sessions, how flexible were you in discussing issues not related to anxiety or directly related to the child's primary diagnoses?"). Results of the study revealed that therapists reported being flexible in their implementation of the treatment plan (both in general and with specific strategies). Secondly, and perhaps more unexpectedly, the indices of flexibility were *not* related to whether the children were co-morbid with other disorders or treatment outcome. The important point here is that flexibility, however defined, is amenable to careful and systematic inquiry. Kendall (1998) asserts that other issues raised by the manualization of treatment are also amenable to empirical investigation and they need not remain in the area of "heated" speculation.

A second example may help to illustrate how issues such as flexibility might be addressed empirically. In these studies, manual-based treatments have been "individualized" in a flexible manner by matching certain characteristics or profiles of the individuals being treated to specific elements or components of previously established effective treatments. These efforts have been labeled "prescriptive matching" by Acierno, Hersen, Van Hasselt, and Ammerman (1994). At the core of this approach is the assumption that an idiographic approach to treatment is more effective in producing positive treatment outcomes than a nomothetic approach (e.g., not all patients who receive a diagnosis of generalized anxiety disorder, for example, are *really* the same - the homogeneity myth put forth some years ago by Kiesler, 1966).

In the child and adolescent arena, Eisen and Silverman (1993, 1998) provided preliminary support for the value of prescriptive matching in the treatment of fearful and anxious children. In the first study, the efficacy of cognitive therapy, relaxation training, and their combination was examined with four overanxious children, 6 to 15 years of age, using a multiple baseline design across subjects. The children received both relaxation training and cognitive therapy (counterbalanced), followed by a combined treatment that incorporated elements of both treatments. Results suggested that interventions were most effective when they matched the

specific problems of the children. That is, children with primary symptoms of worry responded more favorably to cognitive therapy whereas children with primary symptoms of somatic complaints responded best to relaxation treatment. Similar findings were obtained in the second study (Eisen & Silverman, 1998) with four children between 8 and 12 years of age who were diagnosed with overanxious disorder. The interventions that were prescribed on the basis of a match between the treatment and the response class (cognitive therapy for cognitive symptoms, relaxation therapy for somatic symptoms) produced the greatest changes and resulted in enhanced treatment effectiveness. These findings must be considered preliminary because of limitations associated with single case designs; to our knowledge, no controlled group design studies have been conducted examining these issues. Nonetheless, these studies show yet another possible way of individualizing treatment and exploring flexibility in the use of empirically-supported treatment manuals.

In a related vein, Chorpita, Taylor, Francis, Moffitt, and Austin (2004) demonstrated the successful application of a "modular" intervention for childhood anxiety that allowed for systematic adaptation of the protocol to client characteristics. The modular approach involved defining each practice technique as an independent module that could be integrated with other techniques through a flowchart that served to guide module selection. In that investigation, seven youth with anxiety disorders were successfully treated using a multiple baseline design. Data on patterns of use indicated that the protocol administration was highly individualized. For example, although all children participated in techniques such as psychoeducation, exposure, and maintenance exercises, only 29% participated in differential reinforcement strategies and 43% participated in formal cognitive exercises. Moreover, 29% received only the four core components of the manual (self-monitoring, psychoeducation, exposure, and maintenance). The sessions delivered ranged from 5 to 17, and occurred in durations ranging from 7 to 30 weeks (Chorpita et al., 2004). Thus, treatment was highly individualized and found to be effective.

*Issues with efficacy and effectiveness: the transportability of treatments.* The third major concern raised by Ollendick (1999) about the evidence-based treatment movement is embedded in the difference between *efficacy* studies and *effectiveness* studies (Hibbs, 1998; Hoagwood, Hibbs, Brent, & Jensen, 1995). Efficacy studies demonstrate that the benefits obtained from a treatment administered in a fairly standard way (with a treatment manual) are due to the treatment and not due to chance factors or other factors that threaten the internal validity of the demonstration of efficacy. These studies are conducted under tightly controlled conditions, typically in laboratory or university settings. Most of these studies consist of RCTs and clearly specify the sample characteristics in accordance with the definition of "good" experimental designs. In recent years, concern has been raised about the exportability of these "laboratory-based" treatments to the real world of clinical practice. Some argue that the "subjects" in randomized clinical trials do not represent real-life "clients" or that the "experimenters" in these trials do not represent "clinical therapists" in practice settings. Moreover, it has

been argued that the settings themselves are significantly different, ranging from tightly controlled laboratory conditions to ill-defined and highly variable conditions in practice settings. Weisz, Donenberg, Han, and Weiss (1995) have referred to practice settings as the "real test" or the "proving ground" of interventions. This distinction reminds us of the importance of building a strong bridge between science and practice, a bridge recommended over 50 years ago in the Boulder model of clinical training. Building this bridge is admittedly not easy, and a gap between efficacy and effectiveness studies remains.

Nonetheless, it is clear that effectiveness studies that demonstrate the external validity of psychotherapies are very important; moreover, they need to be conducted in a way that allows us to conclude that the treatments are responsible for the changes observed in our clients, not chance or other extraneous factors. In this search for effectiveness, it will be important to emphasize both internal and external validity, as both should be viewed as equally important (Ollendick & King, 2000). Of course, not all treatments shown to be efficacious in clinical trials research will necessarily be shown to be effective in clinical settings. Reasons for such failure may include problems in implementing the treatment procedures in less-controlled clinical settings and the "acceptability" of the efficacious treatments to clients and therapists in those settings. In the final analysis, whether the effects found in RCTs and conducted in research-based settings generalize to "real-world" clinical settings is an empirical question that awaits additional research (see Kendall & Southam-Gerow, 1995, and Persons & Silberschatz, 1998, for further discussion of these issues).

The issues surrounding transportability and efficacy versus effectiveness studies are numerous (e.g., training of therapists, supervision of therapists, homogeneous/heterogeneous samples, development of manuals, adherence to manuals, competence in executing manual-based treatment, and the acceptability of manual-based treatments to clinicians and clients, among others). Weisz et al. (1998) have identified a set of characteristics associated with child psychotherapy outcome research that distinguishes efficacy from effectiveness research. Weisz et al. characterize "research" therapy as serving a relatively homogeneous group of children who exhibit less severe forms of child psychopathology and who present with single-focus problems. Moreover, they suggest that such studies are conducted in research laboratories or school settings with clinicians who are "really" researchers, who are carefully trained and supervised, and who have "light" client loads. Finally, such studies typically use manualized treatments of a behavioral or cognitive-behavioral nature. In contrast, "clinic" therapy is characterized by heterogeneous groups of children who are frequently referred for treatment and who have a large and diverse range of clinical problems. Treatment in such settings is delivered in a clinic, school or hospital setting by "real" therapists who have "heavy" caseloads, little pre-therapy training, and who are not carefully supervised or monitored. Finally, treatment manuals are rarely used and the primary form of treatment is non-behavioral.

Clearly, a number of differences are evident. Although such distinctions are important, they also tend to be broad generalizations that may or may not be true

for various studies conducted in laboratory or clinical settings. Moreover, they may serve to accentuate differences in types of studies rather than to define areas of rapprochement and, inadvertently, create a chasm, rather than a bridge, between laboratory and clinic research. We shall illustrate how these distinctions become blurred by describing two studies: (a) a "research" therapy studied conducted by Kendall et al. (1997), and (b) the previously referred to "clinic" therapy study conducted by Weiss et al. (1999).

In the Kendall et al. (1997) study, the efficacy of a cognitive-behavioral treatment for anxious children was compared to a wait-list condition. Efficacy of treatment was determined at post-treatment and at 1-year follow-up. Using a RCT, the researchers developed a detailed but flexible manual, and the therapists were well-trained and supervised graduate clinicians who carried "light" clinical loads. Treatment was conducted in a university-based clinic. Ninety-four children (aged 9 – 13 years) and their parents referred from multiple community sources (not volunteers or normal children in school settings) participated in the study. All participants received primary anxiety disorder diagnoses (attesting to the relative severity of their problems), and the majority were co-morbid with other disorders (affirming multiple problems in these children, including other anxiety disorders, affective disorders, and disruptive behavior disorders). In short, a relatively heterogeneous sample of children with anxiety disorders was treated. Treatment was found to be highly effective both at post-treatment and 1-year follow-up. It is evident that this study utilized some of the characteristics associated with "research" therapy but also some of the characteristics of "clinic" therapy.

In the Weiss et al. (1999) study previously described, treatment as routinely practiced in an outpatient setting (a school setting) was evaluated by comparing it to an attention control placebo (academic tutoring). The seven therapists were hired through standard clinic practices (six were masters' level clinicians and one was a doctoral level clinical psychologist) and were allowed to select and use whatever interventions they believed were necessary (most selected and used psychodynamic-humanistic or cognitive strategies). No manuals were used. They received no additional clinical training as part of the clinical trial and were provided with a minimal amount of supervision. One hundred and sixty children were randomly assigned to one of the two "experimental" conditions. Children were identified in the school setting and presented with problems of anxiety, depression, aggression, and inattention. Diagnostic data were not obtained; however, the identified children were thought to represent a heterogeneous sample of children with multiple and serious problems. As noted earlier, traditional therapy, as implemented in this study, was determined to be largely ineffective. It is evident that only some of the characteristics of "clinic" therapy were applicable to this study and at least some of the characteristics of "research" therapy were examined.

These studies illustrate that demarcations between efficacy and effectiveness studies are not always clear. Perhaps more importantly, they illustrate the types of studies that need to be conducted that will bridge the gap between research and clinic settings.

Recently, Chorpita (2003) has noted that the efficacy-effectiveness distinction involves at least four different levels of consideration. With true efficacy research, the point is to determine the relation between therapeutic practices or strategies and outcomes (e.g., Chambless & Hollon, 1998; Chambless & Ollendick, 2001). With such research, "upstream" elements are typically controlled (i.e., children and families are carefully screened and selected, therapists are highly trained, and supervision is intensive and often provided by a national expert). Under conditions that maximize these upstream elements, we have considerable confidence that fidelity to a particular protocol matched to a certain problem is related to positive results.

The second type of research, which would be considered effectiveness research by many and has been termed "transportability research" by Schoenwald and Hoagwood (2001), speaks to whether a particular intervention might be promising for delivery in a true clinical practice setting. Essentially, transportability research allows for inferences about the performance of a protocol under a wider range of client conditions that closely approximate client conditions in a practice setting, but at the same time still maximizing therapist and supervisor performance in a contrived laboratory setting. This approach would allow us to say, for example, that "interpersonal psychotherapy is a promising approach for real world cases of depression in youth."

A third type of approach to be considered involves the use of system employees (e.g., school counselors, private practitioners) as therapists. Schoenwald and Hoagwood (2001) termed this approach "dissemination" research, in that it relates to the performance of a protocol once deployed into a system. This research is likely what is most commonly implied when one encounters the term "effectiveness," and it allows for inferences about the performance of the intervention under highly naturalistic conditions (e.g., Henggeler et al., 1998). Nevertheless, in such research the supervision is still provided by the investigator team, and thus questions remain about whether the same practice standards would be maintained after the investigator team withdrew from the system.

The final question regarding system independence can only be addressed directly by "system evaluation" research, in which the system to be evaluated and the investigative team are fully independent. This strategy would allow the final inference to be made: whether treatment operations can lead to positive outcomes when a system stands entirely on its own. Although studies of entire systems exist (Bickman, 1996; Bickman, Lambert, Andrade, & Penaloza, 2000; Burns et al., 1996), they do not truly represent evidence-based system evaluation research, because they have not used evidence-based interventions in one of the experimental conditions, but rather have compared different arrangements of "treatments as usual." Consequently, the outcomes of these studies primarily show differences in practice patterns (e.g., access to system, dropout rates) but are unresponsive with respect to differential outcomes at the level of the child (Bickman, 1999).

This absence of favorable child outcomes noted earlier in treatment as usual practices such as the Fort Bragg Demonstration and other similar investigations is perhaps due to the fact that such "systems" studies have not controlled and

specified the “downstream” elements involving specific therapeutic practices. Thus, there is no guarantee that strategies at the higher level (e.g., care coordination, quality assurance) will not be neutralized or compromised by poor strategies at the lower level (cf., Weisz, Han, & Valeri, 1997). Ultimately, the understanding of what works in system contexts awaits not only new research, but new paradigms of research, in which treatments and systems are simultaneously manipulated.

## Conclusions

We have enumerated several issues associated with evidence-based practice and concluded that some treatments are more effective than others, that manualization need not be a stumbling block to providing effective therapy in both research and clinic settings, and that the transportability of treatments from the laboratory setting to the practice setting is feasible (although still being tested). We have also noted that tensions remain about each of these issues, and we have commented upon various avenues for rapprochement.

Somewhat unexpectedly, however, our present review of evidence-based psychosocial treatments continues to reveal that our armamentarium is relatively “light” and that much more work remains to be done. We really do not have very many psychosocial treatments that possess well-established status in research settings let alone clinical settings; however, this is an exciting time as we continue to develop interventions to close the gap between laboratory and clinic practice. Children and adolescents and their families presenting at our clinics deserve our concerted attention to further the true synthesis of these approaches and to transform our laboratory findings into rich and clinically-sensitive practices.

In the area of child and adolescent anxiety disorders, cognitive-behavioral therapy has been shown to be highly effective, qualifying it as a well-established efficacious intervention. At the same time, however, a number of questions remain in determining which forms of cognitive behavior therapy work best and for whom. One promising avenue for future research is an examination of the mediators and moderators of treatment outcomes (Prins & Ollendick, 2003). Other articles in this special issue will examine the extent of empirical support of treatments for the various anxiety disorders. Although studies to date suggest that factors such as comorbidity that might moderate treatment outcome may not be as important as originally thought, additional empirical evidence is needed before concluding that such moderators are not important in treatment outcome studies.

Another promising line of research involves the use of longitudinal designs – designs that will be particularly important in capturing the effects of treatment that may appear over time. Future studies will be needed to better understand the role of time in capturing both short-term and long-term treatment effects. Such effects have recently been demonstrated in the treatment of adolescent depression (TADS, 2004, 2007). Fortunately, promising results are also being detected for the anxiety disorders, as illustrated in the articles that follow.

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