Applying Empirically Supported Treatments to Complex Cases: Ethical, Empirical, and Practical Considerations

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Among the factors contributing to the underutilization of empirically supported treatments (ESTs) are practitioners' concerns about the appropriateness of ESTs for complex patients who are thought to differ in significant ways from the samples in clinical trials. Such patients may challenge our best available treatments and may raise important ethical, practical, and empirical questions. The present article reviews features that may make a case complex and considers influences on the clinician's decision to provide, modify, or abandon an EST with such cases. Given a dearth of data to inform this decision, we highlight several questions faced by clinicians that are in need of investigation. We suggest avenues for future work that may enhance efforts to disseminate and effectively provide ESTs.

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Recent decades have witnessed increasing efforts by clinical scientists to develop, manualize, and evaluate psychosocial treatments for psychological and behavioral problems (cf. Chambless et al., 1998; Kendall, 1998b). These efforts have resulted in a proliferation of treatments that have been empirically supported for specific clinical conditions, providing an important evidentiary base for clinical practice. However, even as the list of empirically supported treatments (ESTs) has grown, surveys suggest that such treatments are underutilized by practitioners (see Mussell et al., 2000; Persons, 1995). Numerous authors have speculated about possible reasons for the slow dissemination of ESTs (e.g., Addis, Wade, & Hatgis, 1999; Barlow, Levitt, & Bufka, 1999; Persons, 1995), citing limited training in ESTs, failure to read the therapy outcome literature, misconceptions about therapy manuals, and mistaken beliefs about therapy (e.g., all treatments are equally effective) and randomized controlled trials (RCTs) (e.g., efficacy results do not generalize to clinical settings).

Although many explanations have been proposed for this dissemination problem, one notable for its mention by both proponents and opponents of the EST movement concerns the belief that the typical patient included in RCTs may look quite different from some patients seen in routine practice settings (Goldfried & Wolfe, 1996; Persons, 1995). This is often attributed to the exclusion criteria of RCTs, which enhance internal validity through increased sample homogeneity, but which have led the efficacy of ESTs to be demonstrated in what some consider to be relatively select samples of patients. This point was illustrated by Westen and Morrison (2001) in a recent meta-analysis of high-quality therapy

outcome studies of three disorders published in the 1990s. They estimated the average inclusion rate of these studies to be 32% for depression, 36% for panic disorder, and 35% for generalized anxiety disorder, suggesting that the average study excluded approximately two-thirds of the individuals who sought treatment for one of these disorders. While exclusion criteria differed somewhat across studies, substance abuse and suicide risk were common exclusions, and comorbid anxiety, mood, or personality disorders, significant physical problems, and past or recent psychotherapy were also exclusions for some studies. Notably, studies with higher exclusion rates and more stringent exclusion criteria were judged to yield better treatment outcomes.

Such findings have led some to express concerns that the ESTs may be less effective or inappropriate for "unselected" patients in community settings (Goldfried & Wolfe, 1996), especially for complex patients presenting with significant comorbidity, suicidality, or other features that would have excluded them from RCTs or increased their risk of deterioration or dropout. Indeed, restrictions in sampling are viewed by some in the field as a grave shortcoming of RCTs, leading them to dismiss ESTs as severely limited for clinical practice and to rely on other means—typically clinical judgment—as the basis for treatment selection and planning (e.g., Fensterheim & Raw, 1996; Havik & VandenBos, 1996; Silberschatz in Persons & Silberschatz, 1998). By contrast, others in the field call attention to many severe cases that are included in RCTs (Stirman, DeRubeis, Crits-Christoph, & Brody, 2003) and caution against the assumption that excluded cases are more severe or more clinically representative than included cases (Wilson, 1995). These authors further note that RCT exclusion criteria have grown less restrictive in recent years (Persons, 1995) and that effectiveness studies are increasingly evaluating ESTs in community practice settings with positive results (cf. Chambless & Ollendick, 2000; Franklin, Abramowitz, Kozak, Levitt, & Foa, 2000; Merrill, Tolbert, & Wade, 2003; Tuschen-Caffier, Pook, & Frank, 2001; Wade, Treat, & Stuart, 1998; see also Shadish, Matt, Navarro, & Phillips, 2000).

In many settings, complex patients are the rule rather than the exception, and disagreement about the generalizability of RCTs to such patients leaves responsible clinicians wondering how to proceed. Although restrictive exclusion criteria, especially in earlier studies, raise important questions about the conditions under which ESTs are likely to be effective, sweeping dismissal of ESTs on these grounds may be argued to "throw the baby out with the bathwater." It seems premature to disregard a treatment that has been shown to be helpful to individuals with similar problems in favor of a treatment with no empirical support for these problems. Moreover, it has consistently been demonstrated that clinical judgment is not nearly as good as we believe it is, is unrelated to the confidence we feel or to the amount of training or experience that we receive, and is almost always inferior to data-driven actuarial approaches to decision making (e.g., Berman & Norton, 1985; Dawes, Faust, & Meehl, 1989; Faust, 1986; Meehl, 1954), suggesting that the decision to override or substantially modify an EST for an individual patient may lead to poorer outcomes than adherence to a treatment backed by nomothetic research (Wilson, 1995). At the same time, our empirical base is limited, and clinicians generally are not offered guidelines for working with complex patients who may or may not be represented in clinical trials. Clinical "how to" articles (cf. Tarrier, Wells, & Haddock, 1998) provide some useful guidance, but their often narrow focus on a single clinical problem or specific therapeutic approach overlooks important similarities shared by complex cases that may profitably be addressed at a more general level.

The present article considers some of the common challenges faced by clinicians who work with particularly complex cases and who feel unsure about how best to use the EST literature to inform their practice. Based on our experience and that of other scientist-practitioner colleagues, we begin with the assumption that there exist clinicians who value ESTs and would like to use them, but who perceive potential obstacles to their implementation with certain patients. After identifying some of the factors that can make a patient more complex, we discuss the three treatment options that are available to practitioners. Given the paucity of research to inform the choice between these options, we do not offer specific treatment recommendations or prescribe a single model for incorporating complex factors into a case conceptualization or treatment plan. Rather, we highlight the ethical and practical considerations involved in choosing among the available treatment options, and outline future research that may improve our ability to help the

most difficult-to-treat patients while enhancing the relevance of treatment research for clinical practice.

THE COMPLEX CASE

When clinical practitioners refer to a case as complex, they usually imply that the patient possesses certain characteristics that make his or her condition more difficult to treat. Although the features that make a case complex may depend in part on the presenting problem, certain features may contraindicate, require adjustments to, or compromise the effectiveness of existing treatments, regardless of the specific clinical problem. In Table 1, we offer a preliminary list of such "complex" features.

It should be emphasized that relatively little is yet known about the implications of these features for treatment outcome. Although a sizable literature has examined patient characteristics as predictors of treatment outcome, this literature has been plagued by contradictory findings and methodological shortcomings (e.g., small samples, inconsistent measurement, minimal replication of results) that limit its usefulness for clinical decision making (see Garfield, 1994, for a review). In addition, research coverage of these characteristics has been spotty and sparse, with marked variability in the number and quality of studies that have examined each feature and its implications for outcome. Even those features that have received the most empirical attention have not generated sufficiently consistent results to guide treatment selection and planning. For example, studies of the impact of comorbidity on treatment outcome have yielded contradictory results both across (e.g., Hien, Cohen, Miele, Litt, & Capstick, 2004; McLean, Woody, Taylor, & Kotch, 1998; Steketee, Chambless, & Tran, 2001) and within (e.g., Mennin & Heimberg, 2000) disorders and have hinted that outcome may vary as a function of specific features of the comorbid condition, such as its severity (Abramowitz, Franklin, Street, Kozak, & Foa, 2000) or temporal priority (Maddock & Blacker, 1991). Finally, researchers conducting RCTs generally have not focused on identifying clinical features that indicate that the treatment is not recommended or should be adapted. As a result, clinicians often proceed without empirical information about complex features, and their implicit beliefs about such features influence their treatment decisions (Schaefer, Koeter, Wouters, Emmelkamp, & Schene, 2003).

Table 1. Common features of complex cases

Symptom presentation features
Severe symptom presentation
Diffuse, nonspecific initial presentation
Chronic course
Comorbid conditions
Severe functional impairment in multiple domains
Symptoms maintained by factors that are difficult to change
Presenting problem generally considered difficult to treat
No EST available for presenting problem
Safety features
Severe, acute suicidal or homicidal ideation
Parasuicidal or self-injurious behavior
Past suicide attempts/frequent hospitalizations
Ongoing physical danger
Physical/medical features
Chronic pain
Multiple, diffuse somatic symptoms
Medical condition causes psychological symptoms
Physical disability maintains psychological condition
Physical factors place limits on treatment
Intellectual/comprehension features
Limited intellectual ability
Low education level
Cognitive impairment
Other barriers to attention or comprehension (e.g., dissociation)
Personality and related features
Interpersonal features undermine therapeutic alliance
Hostility/guardedness
Dependency
Pervasive tendency to externalize problems
Low psychological mindedness
Low self-esteem or self-efficacy
Psychosocial features
History of chronic or repeated trauma
Multiple, significant current stressors
Severe financial instability
Social isolation
Social environment is highly stressful or unstable
Social environment undermines treatment
Motivational/compliance features
Severe hopelessness and demoralization
Low expectancy for improvement
Poor match between therapy rationale and patient's views
Strong belief in problematic beliefs or behaviors
External contingencies reinforce the sick role
Removal of problems and therapy leaves an "empty life"
Half-hearted commitment to therapy
Treatment noncompliance
Treatment history features
Repeated prior treatment failures
Unsuccessful prior treatment with the EST

We believe that promoting empirically based decisions for the treatment of complex cases must begin by systematically describing the features commonly associated with clinical complexity, then investigating the impact of such features on EST effectiveness. We therefore offer the list in Table 1 as a starting point for the present discussion of complexity and treatment, with the hope that this initial conception of complexity might stimulate further debate and investigation. Given the shortage of systematic research in this area, the list relies heavily on psychological theory and professional experiences

and is presented as a preliminary heuristic tool rather than a definitive or comprehensive review. The listed features may not increase complexity in any individual case, may not affect treatment in similar ways or to similar degrees, and may ultimately be found to be unrelated to treatment outcome. Moreover, although we refer to cases as "complex" for ease of discussion, complexity may be more appropriately conceived as a dimension, with complexity increasing as the number of relevant features increases.

Treating the Complex Case

Faced with a patient who possesses some or many of these complex features, the clinician must make a difficult decision. Should she apply the treatment that is empirically supported for the patient's target problem, even if empirical support was established with a sample that differs from her patient in some important ways? Or should she modify or even abandon the EST, thereby providing a treatment whose efficacy is essentially unknown?

In making this important decision, the clinician may consider a number of questions: What is the primary need of the patient at this time? Is there evidence that this treatment will be useful for this patient? Are there specific contraindications to using this treatment with this patient? Because few empirical guidelines are available to answer these questions, subsequent treatment decisions may rely heavily on subjective judgment and differ considerably across clinicians. For example, some clinicians working with complex patients may wonder about the appropriateness or even the safety of using an EST that they would not hesitate to employ with more straightforward cases. Consistent with this perspective, clinical "how to" articles typically emphasize the need to modify, supplement, or otherwise customize available treatments to accommodate the needs of complex patients. What is less often discussed is how such customizing should optimally be done or how much customizing is actually necessary to make an EST appropriate for such patients. As a result, ESTs may be altered in ways that substantially diminish their benefit or may be postponed or dismissed in cases where they might have done considerable good.

We believe that efforts to increase appropriate, routine use of ESTs by practitioners must involve efforts to identify and address perceived obstacles to their application with complex cases. To that end, we consider what these perceived obstacles might be, beginning with a specific example of an underutilized EST and proceeding to a more general discussion of the questions that clinicians inevitably face when deciding whether, when, and how to implement an EST with a complex patient.

Exposure Therapy for PTSD: An Example

The case of exposure-based therapy for posttraumatic stress disorder (PTSD) (e.g., Foa, Rothbaum, Riggs, & Murdoch, 1991; Keane, Fairbank, Caddell, & Zimering, 1989) provides one striking example of the myriad factors that can prevent a demonstrably efficacious treatment from being offered to complex patients. Indeed, prolonged exposure is not only an EST for PTSD, but has by far the strongest evidentiary base for the treatment of PTSD, leading it to be recommended as the first-line treatment for this disorder (Rothbaum, Meadows, Resick, & Foy, 2000). However, despite its strong endorsement by experts in the field, exposure therapy is often passed over in the treatment of complicated cases of PTSD (Zayfert, Becker, & Gillock, 2002).

Feeny, Hembree, and Zoellner (2003) explored reasons for the underutilization of this therapy and identified four commonly held myths that may contribute to clinicians' reluctance to use it. These include perceptions that exposure therapy cannot be adjusted to individual client needs, is inadequate as a stand-alone treatment for PTSD, is not efficacious in "real-world" settings, and leads to symptom worsening and high dropout rates. Advocates of the treatment emphasize that such perceptions do not accurately reflect the principles and outcomes of exposure therapy. Although clinicians may view a history of multiple traumas, comorbid substance use, or personality disorders as contraindications to exposure therapy, such features do not consistently predict treatment outcome or dropout (van Minnen, Arntz, & Keijsers, 2002). Moreover, despite debates over symptom worsening following imaginal exposure versus other PTSD treatments (Devilly & Foa, 2001; Tarrier et al., 1999), research suggests that exposure increases symptoms in a small minority of patients, that the average increase is small and short lived, and that dropout rates for exposure therapy are not higher than those associated with other treatments for PTSD, including seemingly

innocuous treatments like relaxation training (Foa, Zoellner, Feeny, Hembree, & Alvarez-Conrad, 2002; Frueh, Turner, & Beidel, 1995; Taylor et al., 2003).

Why, in the face of such evidence, are clinicians so reluctant to make use of exposure therapy? One reason that "the perception of exposure therapy as a risky treatment continues despite data to the contrary" (Frueh et al., 1995, p. 811) may be that this treatment, like many ESTs, suffers from a dissemination problem (Freiheit, Vye, Swan, & Cady, 2004; Persons, 1995). The problem is exacerbated by reviews written expressly for practicing clinicians (e.g., S. D. Solomon & Johnson, 2002), which emphasize the adverse effect of exposure on some PTSD patients (Pitman et al., 1991) and point to poor treatment outcomes in some exposure protocols (Z. Solomon et al., 1992) without acknowledging potentially significant limitations of these protocols and studies (cf. Feeny et al., 2003; Frueh et al., 1995).

At the same time, even well-informed clinicians may express concerns about the safety and acceptability of exposure for some PTSD patients (Foa et al., 2002). Because patients who are acutely suicidal or homicidal, severely depressed, psychotic, or abusing alcohol or drugs have routinely been excluded from RCTs for exposure therapy, therapists working with such patients must decide whether and how exposure therapy should be attempted. Furthermore, while most patients appear to experience at most a temporary increase in symptoms during exposure therapy, case studies suggest that a small number of patients deteriorate in therapy (Mueser, Yarnold, & Foy, 1991; Pitman et al., 1991). Unfortunately, no guidelines are available to help the therapist determine how much symptom exacerbation is normal (or even necessary; Foa & Kozak, 1986) and how much denotes a need to modify or halt exposure efforts.

It must also be recognized that patients treated outside of clinical trials often have greater choice and control over their treatment than do many research participants. Studies that have given PTSD patients a choice of treatment report that most decline treatments involving some form of exposure (Veronen & Kilpatrick, 1983, as cited in Bryant, 2000). Moreover, despite a clinician's best efforts, patients may choose not to go along with the best available treatment; two studies of exposure therapy in a community practice setting found that most PTSD patients did not complete assigned exposure homework, with greater case complexity predicting worse compliance (Scott & Stradling, 1997). Even more troubling may be the patient who drops out of therapy, especially the complex patient who is in particular need of services. As therapy outcome studies tend to provide little information about the patients who refuse or drop out of exposure-based therapy, it is difficult to predict which patients will require a modified form of this therapy to complete it successfully.

One final consideration concerns the ways in which exposure therapy can and should be modified for use with a complex patient. Proponents of exposure therapy have emphasized the importance of delivering the therapy in a flexible manner that takes the needs of the patient into consideration (Hembree, Marshall, Fitzgibbons, & Foa, 2001; Jaycox & Foa, 1996; Zayfert et al., 2002). However, few suggestions have been offered for how this therapy should be adapted to handle the complex features appearing in Table 1, and most adaptations that *have* been suggested for addressing particular complex features (e.g., Jaycox & Foa, 1996) have not yet been systematically evaluated. While it has been asserted that "tailoring treatment to each patient is a standard for good [prolonged exposure]" (Feeny et al., 2003, p. 86), it is less clear which therapy parameters can be modified, and to what extent, before the therapy that is offered becomes an essentially different treatment than the one that has been empirically supported. Faced with a complex case, the clinician is left to decide if exposure therapy is appropriate, whether modification of the therapy is necessary, and when and how modification should be undertaken so that the demonstrated benefits of exposure are not reduced or eliminated.

Providing the EST in Its Original Form

The previous example highlights several options that are available to practitioners who are contemplating the use of an EST with a complex patient. One option is to provide a full course of the EST for the target problem, as set forth in the therapy manual, before offering any other treatment for this or another clinical problem. There are several benefits to beginning with the EST in its original form, even with complex patients. The most obvious is that this treatment package has been tested and shown to be efficacious for alleviating the target problem. Any deviations from this package may have an

unknown impact on the efficacy of the treatment. Indeed, research suggests that modifying an EST to tailor treatment to an individual patient's presenting problem seldom improves treatment outcome (see Eifert, Schulte, Zvolensky, Lejuez, & Lau, 1997) and may actually result in worse outcome than adherence to the manual (cf. Schulte, Kuenzel, Pepping, & Schulte-Bahrenberg, 1992).

Schulte and his colleagues conducted a series of studies to try to explain the poorer outcome associated with deviations from treatment manuals (see Schulte & Eifert, 2002, for a review). They discovered that clinicians were often quick to shift from a method-oriented treatment approach (e.g., applying problem-focused manualized techniques) to a process-oriented approach (e.g., addressing the patient's motivation for and engagement in treatment) when they perceived that therapy was not progressing well. Unfortunately, clinicians' perceptions of therapy progress were not very accurate and were heavily influenced by their emotional reactions to the patient. The result was that clinicians made frequent and potentially unnecessary detours from the manual that were negatively associated with outcome, rather than providing the consistent, method-oriented treatment that was positively associated with outcome. Schulte and Eifert (2002) concluded that therapists frequently deviate from therapy manuals too quickly, too often, and for what may be the wrong reasons. Until empirically based criteria are identified to inform therapists when to change course, they suggested that clinicians follow EST manuals as closely as possible and modify the treatment only if the patient's motivation and engagement are so low that the manualized techniques cannot be carried out.

Clinicians may feel more confident proceeding with the original EST when their patient shares important similarities with an RCT sample in which the EST yielded low attrition and reliable improvement. However, even when the patient differs in some ways from the RCT sample, one must be careful not to assume that the treatment is inappropriate or will result in less benefit for that patient. Indeed, several studies have revealed comparable EST outcomes for individuals who were included in, and those who were excluded from, clinical trials (see Barlow et al., 1999, for a review). In focusing on patients' unique features and individual differences, we may overlook important similarities shared by individuals with the same clinical condition and underestimate the potential benefits of a standardized treatment for this condition. As Wilson (1995) notes:

> Undoubtedly, some particularly difficult and complicated cases come to the attention of clinical practitioners. These cases may well require interventions that go beyond what is available in the form of empirically validated techniques. It is also possible, however, to overstate the uniqueness of patients in practice. All too often this serves to undercut the potential influence of clinical research findings, and to justify therapists doing what they are accustomed to doing regardless of the research evidence (p. 182).

Modifying the EST

While starting with an original EST makes conceptual sense, it is unclear whether there are any contraindications to this approach. Should the unmodified EST *always* be attempted first? If not, what factors would suggest that modification is necessary?

The statistical results of an RCT speak to the likelihood of obtaining the same results in another set of patients identified by the same inclusion/exclusion criteria (Mulder, Frampton, Joyce, & Porter, 2003). Hence, with increasing differences between one's patient and the RCT sample, it becomes increasingly important to ask whether the study's results are relevant to and representative of the patient. The issue of generalizability is of particular concern when treating a complex patient, as the most complex cases (e.g., those with significant safety concerns, psychotic disorders, comorbid substance use disorders) continue to be excluded from many RCTs. Concern is heightened when one's patient exhibits characteristics that have been associated with a lack of improvement (or even deterioration) in the RCT or shares important similarities with participants who dropped out of the RCT. At present, no standards exist for determining, on the basis of similarity to the total RCT sample or to the subsample exhibiting poor outcomes, whether to proceed with an existing EST or to attempt some form of modification.

Modification may be most defensible when significant barriers to the implementation of an EST become apparent. For example, if a clinician believes that a

patient would benefit from the EST, but the patient refuses the therapy, responds poorly to the therapy, or threatens to drop out of therapy if the treatment is continued as is, the clinician may ask herself what steps can be taken to enable this patient, who would not otherwise receive this EST, to accept and benefit from it. Similar concerns would arise if a patient is unwilling or unable to attend sessions regularly, does not complete assigned homework, or does not demonstrate agreement with or understanding of the treatment rationale. Modification may therefore be conceived as a two-step process: (a) deciding when modification is necessary and (b) deciding how to modify the treatment.

When Is It Necessary to Modify the EST? The decision to modify an EST is complicated by the difficulty of determining which therapy challenges represent temporary obstacles that can be surmounted using the standard EST and which constitute significant barriers to implementation that require treatment alterations. For example, an EST may be modified when the patient does not accept the treatment rationale or is unwilling to engage in the EST. Lack of acceptance by the patient might be expected to lead to poor motivation to engage in the treatment, and hence to poor compliance with therapy tasks, worse treatment outcomes, and a greater likelihood of dropout if the clinician proceeds with the original EST. Clinicians may also modify an EST if they believe that the patient is not yet ready to begin the treatment as tested or the patient states that he is not yet ready. If the patient's symptoms or environment are so unstable as to warrant safety concerns, if other problems appear more urgent or have a higher clinical priority, or if the patient does not appear to have sufficient coping resources to tolerate a stressful or intensive treatment, the therapist may also choose to modify the EST—or to provide a "preparatory" treatment with the goal of moving toward use of the EST—rather than abandoning or indefinitely postponing its use. Patients who are acutely suicidal, for instance, may require some stabilization prior to the use of exposure therapy (cf. Holohan & Ruscio, 2006), whereas patients whose extreme anger may reduce the efficacy of exposure therapy (Jaycox & Foa, 1996) could be provided with anger treatment (Chemtob, Novaco, Hamada, & Gross, 1997; Yehuda, 1999) before undergoing exposure for PTSD. Achieving successes with preparatory treatments may have the added benefit of increasing patients' confidence in the therapist and therapy approach, thereby increasing their willingness and readiness to undergo the EST itself.

Despite these advantages of preparatory treatments, a potential limitation is that it can be difficult to determine when a patient is sufficiently stable to begin the EST. The absence of research to guide this decision, paired with the understandable caution of the clinician, may lead to a long delay in the use of the EST. Moreover, in some cases, instability may not improve until the symptoms causing the patient's distress are addressed. This leaves the clinician in an ethical bind: Is it preferable to withhold a stressful treatment such as exposure therapy from a trauma patient whose safety factors (suicidality, homicidality, parasuicidal behavior) are considered contraindications for this therapy (Weaver, Chard, & Resnick, 1998)? Or should this treatment be provided regardless of such factors because it offers the best chance of reducing the patient's suffering? As PTSD patients with acute safety concerns are rarely, if ever, included in RCTs for exposure therapy, the decision to proceed with this EST is left solely to therapists, whose desire to "first do no harm" and fear of legal repercussions may cause them to err on the side of caution and avoid providing a potentially risky treatment. This is unfortunate in light of case studies suggesting that modified exposure therapy can be successfully provided to acutely suicidal PTSD patients with impressive results (e.g., Holohan & Ruscio, 2006).

How Should the EST Be Modified? There are at least three ways in which an EST may be modified for use with complex cases, and these options are not necessarily mutually exclusive. The first is an "augmented" approach in which an EST targeting the patient's primary condition is augmented by supplementary interventions that aim to address other problems or complex features of the patient. This might include (a) sequential administration of multiple ESTs or (b) concurrent delivery of multiple treatments by incorporating supplementary treatment elements into an EST. The first method retains the EST in its original form, but presents it in a "bundled" fashion with other ESTs; what is "modified" in these instances is the provision of multiple ESTs rather than the single treatment that is offered to most RCT participants. The

second method involves modification of the EST itself. Becker (2002) presented an elegant illustration of the latter method, weaving in elements of dialectical behavior therapy and trauma-focused exposure therapy to permit the delivery of exposure and response prevention treatment to a patient with comorbid obsessive-compulsive disorder (OCD), PTSD, and borderline personality disorder. She emphasized the value of proceeding sequentially through one "core" or "anchor" EST, while bringing in elements from other treatments as needed, to maintain a coherent organizing framework and a focused therapeutic goal.

A second modification strategy may be described as a "tiered" approach. This approach suggests that if a clinician has reason not to use the "preferred method" or first-line treatment for a target condition, she should move down to a "good method" rather than employing a method with no empirical support. An example would be to use cognitive therapy or stress inoculation training with a PTSD patient if exposure is not feasible or acceptable to him. Both of these therapies have empirical support and may be useful when working with trauma survivors who are unwilling to confront trauma reminders or to tolerate the temporary increase in anxiety that may accompany exposure (Rothbaum et al., 2000). In some cases, a tiered approach may not only lead to improvement in the patient's condition, but may lay the groundwork (e.g., safety, stabilization, a strong therapeutic alliance, success experiences) for attempting the best available treatment at a later time, if necessary.

A third option for modification is an "accommodation" approach in which the EST is itself adjusted to accommodate the needs, limitations, and strengths of the patient. This approach retains the core elements of the treatment, but implements specific interventions in ways that deviate significantly from the EST manual. For example, a patient with little education, limited cognitive ability, or very concrete thinking may be taught a highly simplified, "pared down" version of cognitive restructuring that deemphasizes or excludes more abstract concepts or tasks.

This third approach, perhaps more than the others, raises a critical but often neglected question: When does a modified EST cease being an EST? That is, what changes may be made to the treatment before it can no longer reasonably be regarded as the protocol that was empirically supported? Because few ESTs have been investigated using component control (e.g., dismantling, additive) designs that isolate active ingredients of change, it is hard to know what the active ingredients actually are and which aspects of the treatment can be modified without weakening or eliminating these essential treatment elements. Although authors routinely espouse the flexible application of treatment manuals and the adjustment of interventions to fit the needs of particular patients, the line between superficial accommodation and meaningful alteration of an EST is rarely explicit. As the number and extent of such modifications increase, so does uncertainty about the likely efficacy of the modified treatment. For this and other reasons, there have been increasing calls for movement away from manualized treatment packages and toward empirically supported procedures or even empirically supported principles of change (e.g., Rosen & Davison, 2003; Westen, Novotny, & Thompson-Brenner, 2004). For the time being, authors of treatment manuals can facilitate appropriate modification of ESTs by (a) specifying the therapeutic elements and change mechanisms that are considered essential to the treatment and (b) including, to the greatest extent possible, examples of acceptable modifications that preserve these essential elements, with special emphasis on modifications that were used during testing of the treatment. An elegant example of this appears in the Seeking Safety protocol, which offers guidance on options for individualizing the treatment, examples of particularly complex cases that have arisen in past research, and information about specific modifications of the protocol that have/have not been successful (Najavits, 2002).

When the decision is made to modify an EST, how should clinicians choose from among these three approaches to modify responsibly? While individual judgment and the individual case will inevitably play a role in the decision-making process, there is a great need for empirically derived decision guidelines to inform and facilitate this process (Eifert et al., 1997). Until such guidelines become available, the most defensible strategy may be to modify an EST only when there are persuasive reasons to do so, and only to the extent that is actually necessary. It may also be prudent to view any substantially modified EST as a novel treatment whose efficacy is largely unknown and whose implementation

should follow espoused practices for novel treatments, such as working within a coherent theoretical framework grounded in the extant research literature (Kimble, Riggs, & Keane, 1998), conducting therapy as a scientific experiment with $n = 1$ (Hayes, Barlow, & Nelson-Gray, 1999), and assessing the patient's progress continuously throughout treatment (cf. Howard, Moras, Brill, Martinovich, & Lutz, 1996).

Abandoning the EST

There may be times when practitioners choose to completely abandon an EST. At present, little is known about the conditions under which a given EST is contraindicated and should be disregarded, nor the conditions under which an EST that has been attempted should be terminated. Given the dearth of empirical guidelines to direct this decision, the personal beliefs or preferences of the therapist will again predominate. For example, Weaver et al. (1998) noted that many well-intentioned therapists avoid exposure work with trauma survivors because they are afraid of increasing the patient's distress, "retraumatizing" the patient, or releasing a flood of affect that they or the patient will be unable to handle. However, in a recent, well-controlled RCT with few exclusion criteria (Taylor et al., 2003), symptom worsening in prolonged exposure was rare and not worse than in relaxation training or eye movement desensitization and reprocessing (EMDR). The enduring perception nevertheless results in many patients not being offered the best available EST for their condition.

An alternative scenario is one in which the EST is offered and appropriately applied, but the treatment is failing or has failed. The failure of an EST raises a host of additional questions about how treatment should proceed. If the treatment failure occurred with a previous therapist, the current clinician must decide whether to attempt the EST again in either its original or a modified form, recognizing that additional treatment failures may increase demoralization, reduce motivation and hope, and perhaps raise the risk of dropout. If the treatment failure instead occurred with the current therapist, that clinician must decide whether or not to attempt a modified version of the treatment before abandoning it completely (see Heimberg, 1998). This decision might be informed by considering the extent to which the causal processes that appear to underlie the patient's problems are addressed by the causal mechanisms involved in the treatment (Haynes, Kaholokula, & Nelson, 1999). It may again, however, be difficult to identify the point at which an adequate trial of the EST has been attempted and modification is needed. Similarly, it is unclear how and when to decide that the modified treatment has failed and the EST should be entirely discarded.

Finally, if the decision is ultimately made to abandon the EST, the clinician must decide what should be done in place of the EST and how this alternative treatment should be selected to confer the greatest chance for success. The clinician might consider a tiered approach to treatment planning that incorporates components of available ESTs rather than implementing an entirely novel treatment with no empirical support. Research is needed to determine whether such a component-selection approach is preferable to "treatment as usual" for practitioners who have opted out of using an EST with a complex case.

FUTURE DIRECTIONS

Clinicians have long been aware of the existence of complex cases and of the challenges that they present to our best available treatments. However, questions about potential limitations of available ESTs for treating complex patients have often polarized supporters and opponents of the EST movement, diverting attention away from genuine concerns raised by clinical scientists and empirically minded clinicians. We believe that ESTs hold great promise for the successful treatment of complex cases and that the widespread, appropriate use of these therapies with our most challenging patients is an important goal for our field. Achieving this goal will require (a) open discussion about how best to employ ESTs with complex patients, (b) development of empirically based clinical guidelines to facilitate successful application of ESTs by clinicians in the field, and (c) research to enhance understanding of complex clinical features and their implications for therapy.

Discussing the Issue at a Fieldwide Level

The first step toward increasing the use of ESTs with complex cases is to identify this as an important fieldwide issue, one facing scientist-practitioners who work with a variety of presenting problems, patient populations,

therapeutic interventions, and treatment settings. Important commonalities of complex features across diverse patient presentations provide common ground for conversation across formerly isolated problem domains. For example, exchanges of innovative strategies for treating PTSD cases with overwhelmingly intense affect (e.g., Hembree et al., 2001) could be broadened to consider the potential utility of such strategies for addressing overwhelming affect in other disorders. Shared recognition of complex factors may also strengthen the bridge between the science and practice communities, increasing dialogue about the current strengths and limitations of available ESTs for treating the most challenging cases under typical practice conditions. Such dialogue may, in turn, facilitate more rapid and targeted improvement of existing treatments as well as more widespread provision of ESTs to complex patients.

Awareness and discussion of complex patient features are beginning to take shape at a fieldwide level, particularly for the highly visible feature of comorbidity. While this is a promising first step, comorbidity is only one of many factors that can undermine the efficacy of our best available treatments; similar dialogue is needed for other factors as well. Broad-based, clinically relevant discussion of complex features in journals, conferences, and continuing education venues should increase recognition of these features as challenges faced by the larger scientist-practitioner community and facilitate exchanges of ideas for improving treatment outcomes of complex patients.

Learning from Clinicians Who Treat Complex Cases

Therapists who use ESTs are an important source of information about the strengths and limitations of these treatments in routine care settings. Listening to their experiences, observations, and concerns may help researchers to identify (a) patient characteristics that may be associated with poor outcomes in an EST, (b) treatment modifications that may make an EST more effective for certain complex patients, or (c) novel therapies that appear to have promise for treating certain complex patients but require systematic study on a larger scale. Indeed, clinicians may be the first to "discover important individual nuances that remain hidden from the laboratory scientist simply because the tight environment of the experimental testing ground makes it impossible for certain behaviors to occur or for certain observations to be made" (Davison & Lazarus, 1995). This may be especially the case for complex features that are screened out of the RCT by exclusion criteria or included in such small numbers that their effects are difficult to detect.

Given the large number of patient factors that may introduce complexity into treatment, as well as the expense of gathering sufficiently large samples to examine associations between patient characteristics and treatment outcomes, practitioners may help to narrow the pool to those factors that are especially common or problematic and therefore in greatest need of study. Clinicians may also provide important feedback about treatment manuals and suggest elaborations or clarifications that would enhance their utility with very challenging patients.

Making Treatment Outcome Research Even More Applicable to Complex Cases

Several steps can be taken to make therapy outcome research more inclusive of and relevant to the treatment of complex patients. First, we urge researchers to minimize the exclusion criteria of clinical trials and to clearly describe and justify the employed criteria in their research reports. Although there are obvious trends toward greater inclusiveness in treatment outcome research, even some fairly recent studies have had rather restrictive exclusion criteria (Westen & Morrison, 2001). More exclusionary studies have reported higher rates of patient improvement, larger treatment effect sizes, better posttherapy functioning, and less subsequent treatment seeking than studies with less stringent criteria, leading Westen and Morrison (2001) to suggest that the blanket term "empirically supported" may need to be qualified (e.g., by specifying the nature of the sample) to provide a clearer sense of the likely generalizability of research results. They also suggested that investigators report the percentage of patients omitted from their treatment study by *each* exclusion criterion, information that is rarely provided in RCT reports but is essential for the evaluation of external validity as well as for informed clinical decision making (see also Mulder et al., 2003; Stirman et al., 2003).

Second, we join others (e.g., Addis et al., 1999; Persons, 1995) in calling for greater use of "clinic-based" effectiveness research to supplement more traditional "laboratory-based" efficacy research. As has been noted

elsewhere (Aikins, Hazlett-Stevens, & Craske, 2001; Borkovec, Echemendia, Ragusea, & Ruiz, 2001), effectiveness studies are likely to be most informative when efforts are made to safeguard internal validity while maximizing external validity, enhancing understanding of mechanisms of change as well as increasing confidence that the observed response is attributable to the treatment provided.

Third, standard RCT designs can be used to rigorously and systematically study the treatment response of complex cases. For example, patients can be stratified on the basis of problem complexity (e.g., suicidal versus nonsuicidal), on particular combinations of presenting problems (e.g., PTSD plus chronic pain versus PTSD alone), or on any other theoretically relevant clinical features, then randomly assigned to treatment conditions within this stratification scheme (Jacobson & Christensen, 1996). Alternatively, RCTs can evaluate the efficacy of treatments that are flexibly applied in response to certain patient features. As Persons noted, RCT methods need not be restricted to testing standardized treatment protocols, but can be used to study open-ended, self-correcting, and nonmanualized treatments in a systematic fashion (Persons & Silberschatz, 1998).

Fourth, researchers and clinicians alike can make greater use of methodologically rigorous single-case designs to provide fine-grained exploration of a standard or a modified EST conducted in the presence of one or more complex features. Promising treatment modifications or apparent associations between complex features and treatment outcome could then be further evaluated using large-group designs.

Finally, it would be valuable to conduct research into how therapists make choices about treatment selection and planning for complex patients. Such research could examine decision making not only at the level of full treatment packages (e.g., choosing between different ESTs or between treatments with and without empirical support), but also at the level of specific treatment components (e.g., relaxation training, cognitive restructuring) or even narrower therapeutic interventions, to inform treatment development and dissemination efforts.

Increasing Basic and Applied Investigation of Complex Factors

There is a great need for research focusing on complex factors and their implications for treatment. This might fruitfully include basic research into the nature and prevalence of specific complex factors as well as applied studies with complex patients that explore treatment process and outcome, patient–treatment matching, differential application of treatment manuals, and the use of patient characteristics as predictors of therapy attrition and outcome. Such research may aid in the development of conceptual models that organize, describe, and explain complex factors and their interactions in ways that stimulate further investigation and inform clinical decisions.

One particularly pressing research agenda is the need to determine which of the patient characteristics that have been identified as complex features do, in fact, negatively influence treatment outcome. For example, several studies examining the feature of comorbidity have found not only that the effects of ESTs often generalize to patients with comorbid conditions, but also that provision of an EST for a target condition can lead to simultaneous or subsequent improvement of the comorbid disorders themselves (e.g., Borkovec, Abel, & Newman, 1995; Brown, Antony, & Barlow, 1995; Wade et al., 1998). However, other studies have found comorbidity to negatively affect treatment response, to substantially lengthen the duration of treatment, or to increase the likelihood of relapse after treatment (see Aikins et al., 2001; Westen & Morrison, 2001). These mixed findings suggest the need for targeted research to identify the particular combinations of conditions that are associated with poorer outcome in specific ESTs.

An important way to examine the implications of complex factors for treatment outcome is to explicitly document and track these factors in RCTs. As many have noted (e.g., Davison & Lazarus, 1995), while the group-based statistics employed in RCTs provide necessary information about the overall efficacy of a treatment, they do not say much about a given individual in the group. Fine-grained inspection of the therapy course of individual cases (or subsets of cases who share a complex feature) may usefully supplement analyses of the full sample or of treatment conditions that are currently standard in RCTs. The resulting information, when compared and pooled across clinical trials, may help to elucidate those complex factors that are unassociated with treatment outcome and those that raise the risk for minimal response, deterioration, or dropout from the EST. It may also inform the development of statistical

models that use initial clinical features to help predict the treatment course and response of individual patients (Howard et al., 1996).

Finally, we concur with Addis et al. (1999) that a higher priority should be placed on studying individuals for whom ESTs are found to be ineffective. Our scientific community should require RCTs to identify individuals who (a) refuse the treatment and are excluded from the RCT, (b) drop out of the treatment, or (c) complete the treatment but exhibit a poor or negligible response. Mandating reporting of this information in RCT reports would substantially increase the empirical base for informed clinical decision making. In addition, it would permit follow-up investigation of failure-predicting factors (e.g., using the RCT/stratification approach described previously), development of innovative or modified treatments aimed at improving outcomes for patients possessing these factors, and subsequent evaluation of these new or modified treatment protocols in RCTs. For example, if certain comorbid conditions were found to predict EST failure among PTSD patients, follow-up research could determine whether outcome was best improved by (a) presenting multiple, intact treatments (examining which combination, order, and timing of treatments maximizes outcome); (b) modifying existing treatments to accommodate all presenting problems (examining how and when modifications should be made); (c) combining existing ESTs in a systematic manner (e.g., merging treatments for PTSD and panic; Falsetti & Resnick, 2000); or (d) developing entirely new treatments that address specific problem combinations (e.g., creating a new therapy for comorbid PTSD and substance abuse; Najavits, 2002).

Enhancing the Utility of Treatment Manuals for Working with Complex Cases

To further promote effective decision making and increase the number and range of patients to whom ESTs are offered, treatment manuals might usefully increase their coverage of guidelines for applying manualized treatments to complex cases. A growing literature has challenged the common perception that treatment manuals are rigid, formulaic, or unresponsive to the needs of individual patients, underscoring the individualization and creativity afforded by such manuals and the flexible manner in which they may be applied (Heimberg, 1998; Kendall, Chu, Gifford, Hayes, & Nauta, 1998; Wilson, 1996). Having dispelled this misperception, however, it is important that manual developers more clearly specify which aspects of a treatment may be customized to address unique aspects of the case, and which aspects require close adherence to manualized procedures to maximize clinical benefit (Addis et al., 1999). As an appropriate balance between flexibility and fidelity may be especially difficult to achieve with complex patients, manuals could offer guidelines for customizing the treatment to improve its efficacy for or acceptability to such patients. This might include providing specific examples of flexible applications of the manual that remain true to the core principles and practices of the evaluated therapy while accommodating challenging patient features (Hudson, Krain, & Kendall, 2001; Kendall, 1998a).

Manuals might also be made more informative by listing some of the most common or noteworthy complex features that may require treatment modification. Suggestions for addressing complexity due to comorbidity (e.g., coexisting problems known to influence treatment outcome) and motivation (e.g., noncompliance with therapy assignments) may be especially useful. As particular complex features are shown to be contraindications for certain treatments, it will be important for therapy manuals (as well as RCT reports and EST lists) to list contraindications in an explicit and accessible manner in order to facilitate appropriate treatment selection by clinicians. Of course, manual writers will be unable to anticipate—let alone address—every complex characteristic that could apply to a particular case, and therapists must ultimately be responsible for considering the available literature and unique features of the patient when selecting and executing a treatment. However, even relatively modest efforts to enhance the utility of therapy manuals for work with complex cases have the potential to yield improved therapy outcomes, greater standardization of care, and greater use of and adherence to treatment manuals by practitioners.

In addition to these important enhancements of existing manuals, more dramatic changes have been proposed for the form and content of manuals that may influence the treatment of complex patients. For example, Barlow, Allen, and Choate (2004) recently introduced a treatment

protocol that takes advantage of key similarities in the mechanisms and processes underlying a diverse set of "emotional disorders." Unlike the specialized manuals for individual disorders that have proliferated in recent years, this protocol includes a set of three therapeutic principles that can be used, with only minor adjustments, to treat each of a number of anxiety and unipolar mood disorders. Streamlined, unified manuals of this sort may not only enhance the ease of learning, applying, and disseminating ESTs, but they may also prove more efficient and perhaps more effective in addressing the multiple problems with which many complex patients present. An alterative proposal has been raised by authors who have called for the development of "clinical blueprints" to replace prescriptive manuals of therapy techniques (e.g., Eifert, Evans, & McKendrick, 1990). These flexible decision rules are intended to guide the design and execution of a treatment that addresses specific problems of the patient and the factors maintaining these problems. Research is needed to determine whether such flexible clinical decision rules outperform prepackaged therapy manuals in treating complex cases.

Using Knowledge of Complex Factors to Better Match Patients with Appropriate Treatment

Finally, as more becomes known about the specific impact of particular complex factors on particular treatments, scientist-practitioners will be able to develop increasingly accurate and effective stepped-care treatment models that match the complexity of a patient with the level and intensity of therapy needed to produce good treatment outcomes (Hayes et al., 1999; Newman, 2000; Wilson, 1995). Such models begin with the assumption that a one-size-fits-all approach to therapy is unlikely to result in optimal treatment outcomes nor in maximally efficient and cost-effective treatment. For example, patients exhibiting a smaller number of complex features may respond well to less intensive treatments (e.g., brief therapies, group treatments) or may require less therapist contact (e.g., fewer or less frequent sessions) to achieve relatively high end-state functioning. By contrast, patients with a larger number of such features may require more intensive treatments (e.g., inpatient, day hospital, or long-term outpatient treatment) or more therapist contact to achieve comparable or even acceptable levels of functioning. As such stepped-care models are developed and tested, it will be important to consider not only the costs associated with providing more treatment than is required, but also the potential social, ethical, and economic costs of providing multiple, inadequate trials of treatment that poorly address the needs of the most severely affected patients.

CONCLUSIONS

Perceived obstacles to the use of ESTs with complex patients—compounded by a lack of empirically based guidelines to inform EST implementation with such patients—result in the underutilization or overmodification of ESTs in the very cases where their demonstrated efficacy is most urgently needed. We propose that the appropriate, routine use of ESTs with complex cases is an important goal that can be reached through increased dialogue between scientists and practitioners at a field-wide level, more systematic evaluation of treatment modification strategies (including noting when a modified EST is no longer an EST), more explicit reporting of contraindications to specific ESTs, and more focused research into the nature and therapeutic impact of complex patient features. Together, these efforts may not only enhance the use of existing ESTs, but may also lead to the development, evaluation, and implementation of increasingly effective treatments for our most difficult-to-treat patients.

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