



## Balancing fidelity and adaptation in the dissemination of empirically-supported treatments: The promise of transdiagnostic interventions

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### A B S T R A C T

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Assessing treatment fidelity is a core methodological consideration in the study of treatment outcome; it influences both the degree to which changes can be attributed to the intervention and the ability to replicate and disseminate the intervention. Efforts to increase access to evidence-based psychological treatments are receiving unprecedented support; but pressures exist to adapt treatments to service settings, running the risk of compromising fidelity. However, little evidence is available to inform the necessary conditions for the transportation of interventions to service provision settings, and the degree to which fidelity is even evaluated or emphasized in dissemination and implementation programs varies dramatically. Moreover, adaptation is associated with several benefits for dissemination efforts and may address relevant barriers to adoption. A particularly promising strategy for maximizing the benefits of both fidelity and adaptation is the use of transdiagnostic interventions. Such treatments allow for greater flexibility of the pacing and content of treatment, while still providing structure to facilitate testing and replication. Preliminary evidence supports the efficacy of this strategy, which may be particularly conducive to dissemination into service provision settings. At this time, further research is needed to evaluate the relationships among fidelity, adaptation, and outcome, and to determine the potential for transdiagnostic treatments to facilitate dissemination.

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### Introduction

Efforts to disseminate empirically-supported treatments (ESTs) are receiving unprecedented support as the potential public health benefit of better access to effective mental health care has received increased recognition (e.g., Insel, 2009; President's New Freedom Commission on Mental Health, 2004). Internationally, large-scale initiatives are underway and evaluation of the most effective procedures for disseminating and implementing treatments is ongoing. One of the most pertinent questions at this stage is that of transportability – the degree to which treatments that demonstrate efficacy in controlled research designs can be utilized in front-line service provision settings with similar benefits. Studies of treatment effectiveness suggest that it is possible to see gains similar to those observed in efficacy trials (e.g., Clark et al., 2009; Franklin, Abramowitz, Kozak, Levitt, & Foa, 2000; Nadort et al., 2009; Persons, Bostrom, & Bertagnolli, 1999; Wade, Treat, & Stuart, 1998); however, other studies have shown attenuation of treatment effects in service provision settings (e.g., Burns et al., 2002; Henggeler, Melton, Brondino, Scherer, & Hanley, 1997). Indeed, the conditions necessary for successful implementation outside of

research settings are not well understood and studies of effectiveness differ in the degree to which they utilize procedures similar to those used in controlled research trials.

Many factors reflecting differences between clinical research and clinical practice settings may impact the transportability of treatments, such as organizational factors (see Backer, Liberman, & Kuehnel, 1986; Fixsen, Naoom, Blasé, Friedman, & Wallace, 2005). A critical component of efficacy trials is the degree to which treatments are administered competently and as intended. Since the development of more clearly defined psychological treatments in the 1970s and 1980s, treatment fidelity has emerged as an important methodological consideration in the empirical evaluation of interventions. Specifically, the degree to which interventions are administered as intended and in a reliable manner impacts both the internal validity and the external validity of these studies and has implications for the ability to attribute symptom changes to the intervention and to replicate and disseminate treatments (see Moncher & Prinz, 1991; Perepletchikova, Treat, & Kazdin, 2007).

Intensive procedures for training, supervision, and ongoing monitoring are employed to maximize fidelity in efficacy trials. Indeed, many efficacy studies will set a priori standards for sufficient fidelity such that cases for which this standard is not met are not included in data analysis (see Behar & Borkovec, 2003). Although such stringent standards can be employed in these

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controlled settings, training in the context of dissemination efforts presents a particular challenge. The process of training is costly, and traditionally utilized methods for dissemination (i.e., workshops) are not sufficient to effectively train clinicians (see Oxman, Thomson, Davis, & Haynes, 1995; Sholomskas et al., 2005; VandeCreek, Knapp, & Brace, 1990). Indeed, because of the cost associated with supervision, feedback, and fidelity monitoring, many dissemination programs do not include these procedures in their implementation efforts. The degree to which this is damaging, or even potentially fatal, to both the acute success and long-term sustainability of implementing ESTs remains unclear. This is further complicated by the potential benefits of adaptation.

Given the high levels of control needed to conduct efficacy research, interventions inevitably require some level of adaptation in order to be used in service provision settings, where contextual factors influence the feasibility of such controls. In fact, adaptation is not only an expected response to the use of a new innovation, but actually facilitates adoption and prevents drift (Rogers, 2003). Although adaptation may facilitate adoption rates and transportability to heterogeneous clinical settings, it may also attenuate or compromise the effectiveness of interventions through altering the conditions in which they were tested. With the recent proliferation of efforts to disseminate ESTs in the absence of a “gold standard” procedure for this process, the appropriate balance of fidelity and adaptation is a particularly important and timely research question.

Although the introduction of treatment manuals provided an unprecedented opportunity for the standardization and dissemination of psychological treatments (see Luborsky & DeRubeis, 1984), substantial criticism of manualized interventions remains (e.g., Addis & Krasnow, 2000; Barlow, Levitt, & Bufka, 1999). Furthermore, despite the presence of treatment manuals for years, the dissemination of these treatments is spotty. Acknowledgement of the limitations of traditional manualized treatments and advances in basic research have led to the development of novel treatment strategies that introduce flexibility to the structure of ESTs. Transdiagnostic or principle-based treatments aim to treat similar disorders using interventions that may target underlying processes (e.g., negative affect) or that utilize decision rules to determine the use and dose of components based on individual symptom presentations. These treatments introduce opportunities for flexibility in manualized treatments by allowing for greater heterogeneity of clinical presentation and providing opportunities to adapt the intervention to the individual patient. As such, these treatments may facilitate a balance between fidelity and flexibility that maximizes the benefits of both.

This paper will provide a critical review of the importance of fidelity and adaptation in the dissemination and implementation of ESTs. First, the literature on the association between treatment fidelity and outcomes will be reviewed. Second, we will discuss the promise of the burgeoning area of development of transdiagnostic, modular, and principle-based treatments for providing a framework that facilitates a balance between fidelity and adaptation and may provide a particularly cost-effective modality for the dissemination of ESTs. Finally, the importance of fidelity and flexibility for successful dissemination and implementation efforts will be discussed (for review of this issue in substance abuse prevention, see Backer, 2001).

## Treatment fidelity

The results of studies evaluating the importance of treatment fidelity have been mixed, which may be attributable to the inconsistency in how fidelity is defined. Treatment fidelity was initially conceptualized as synonymous with treatment integrity, or the

degree to which an intervention was delivered as intended. Moncher and Prinz (1991) articulated a definition of treatment fidelity consisting of both treatment integrity and treatment differentiation, bringing attention to fidelity as not only reflective of the components that should be administered, but also those that should *not* be administered, or are characteristic of another intervention. A more complex conceptualization of fidelity was presented by Lichstein, Riedel, and Grieve (1994), who emphasized not only the importance of adherence in treatment delivery (i.e., integrity and differentiation), but also the importance of variables related to patient receipt and enactment of the intervention. Thus the degree to which the patient comprehends the intervention and utilizes it as intended both in session and outside of session also contribute to fidelity. Lichstein et al. (1994) suggested that treatment delivery, receipt, and enactment are related, but orthogonal concepts. Thus, a treatment could be administered with high levels of integrity and differentiation, but with low levels of patient receipt and enactment. Moreover, conceptualizations of fidelity vary in the role of clinician competence, with some suggesting that it is a component of fidelity (e.g., Hogue et al., 2008) and others suggesting that it may reflect a related but distinct construct (e.g., Barber, Sharpless, Klosterman, & McCarthy, 2007).

The inconsistency in the definition of fidelity is also reflected in the variability in how it is measured. Commonly used procedures include the identification of the core elements of the treatment and the rating of their completion by clinicians, supervisors (via live or audiotape review), or independent evaluators. Similarly, studies will use this procedure to evaluate treatment differentiation. For example, the ability of an independent evaluator (blind to study condition) to correctly identify the treatment is often used as an index of differentiation. Measurement frequency (e.g., weekly or randomly selected), intensity (e.g., dichotomous or continuation evaluation), and standardization (e.g., use of validated measures) also varies among studies. Patient adherence is typically assessed based on patient self-report (either self-report form or therapist interview) or evidence of the completion of assignments (e.g., completion of monitoring forms).

Despite these limitations, over time, the assurance of a high level of treatment fidelity has become a staple of clinical randomized controlled studies as a basic methodological consideration; although inconsistency in implementation and reporting standards remains a problem (see Perepletchikova et al., 2007). When then transporting these treatments, which are developed and evaluated under conditions of a high standard of fidelity, the expectation of similar outcomes in the absence of similar standards cannot be assumed. Studies have attempted to specifically evaluate the association of treatment fidelity and outcome; below we review the literature on this association.

## Review of fidelity-treatment outcome association

Studies have demonstrated variable results with regard to the link between fidelity and outcome; however, results for effectiveness and dissemination trials appear to imply a stronger relationship relative to efficacy trials. For example, Assertive Community Treatment (ACT; Stein, 1998) is an EST for which a particularly strong fidelity-outcome link has been established in effectiveness and dissemination trials; programs achieving high fidelity outperformed low fidelity programs (e.g., McHugo, Drake, Teague, & Xie, 1999) and in cases of poor fidelity-outcomes have been attenuated (e.g., Burns et al., 2002). Another EST with a particularly strong fidelity-outcome link is Multisystemic Therapy (MST; Henggeler, Schoenwald, Borduin, Rowland, & Cunningham, 1998).

MST has been disseminated widely both within the U.S. and internationally (Schoenwald, Heblum, Saldana, & Henggeler,

2008). A particular emphasis of the MST dissemination efforts has been on implementing training and fidelity in a manner similar to efficacy trials. To evaluate the necessity of this implementation strategy, Henggeler et al. (1997) tested whether a modified training procedure without the rigor of that utilized in efficacy and other effectiveness and dissemination trials would achieve similar outcomes. This study approximated the training typically utilized in service provision settings, which included an initial training workshop absent of follow-up consultation, fidelity monitoring, and booster training sessions. Patients ( $N = 155$ ) were randomly assigned to receive MST or usual services, and although MST outperformed usual care, outcomes were substantially attenuated relative to other studies. Furthermore, adherence to treatment components as rated by parents, adolescents, and therapists was associated with better outcomes. Other studies of the transportation of MST have provided further support for the adherence-outcome association (Schoenwald, Carter, Chapman, & Sheidow, 2008; Schoenwald, Chapman, Sheidow, & Carter, 2009).

The results of the link between fidelity and outcome in efficacy studies of cognitive-behavioral interventions have been more inconsistent. In two studies evaluating symptom change and treatment adherence to specific techniques in cognitive therapy for depression, adherence to treatment procedures significantly predicted subsequent reductions in depression (DeRubeis & Feeley, 1990; Feeley, DeRubeis, & Gelfand, 1999). In contrast, in a multi-site efficacy trial of cognitive-behavioral therapy (CBT) and interpersonal psychotherapy for bulimia nervosa, therapist adherence (reflecting both treatment integrity and differentiation) was not associated with patient outcome for either treatment condition (Loeb et al., 2005).

In a study of therapist variables (e.g., experience, adherence, gender) and treatment outcome in the Multicenter Collaborative Study for the Treatment of Panic Disorder (Barlow, Gorman, Shear, & Woods, 2000), Huppert et al. (2001) found that therapists with superior patient outcomes exhibited similar levels of adherence relative to those with poorer outcomes. In follow-up study, patient motivation was examined as a potential moderator of this relationship (Huppert et al., 2006). Similar to the first analysis, adherence alone was not significantly correlated with outcome, however motivation moderated this association. Among patients with high motivation, adherence was not associated with outcome, and among patients with low motivation, adherence was *negatively* associated with outcome. The authors suggested that this result may be related to a more flexible application of the protocol with “more difficult” patients who exhibited lower motivation to change.

Two recent studies have found non-linear associations between fidelity and outcome. Barber et al. (2006) evaluated the relationship between adherence and treatment outcome as part of a large multi-site study of the treatment of cocaine dependence and noted a curvilinear pattern of results with low and high adherence associated with poorer outcome relative to moderate adherence. Similarly, in a study of CBT and multidimensional family therapy for adolescents with externalizing problems, both linear and curvilinear effects were found for the association between fidelity and treatment outcome (Hogue et al., 2008). For example, a linear effect reflecting superior outcome with greater adherence was noted for substance use in the CBT condition and externalizing behaviors in both conditions. However, for internalizing behaviors, a curvilinear effect was found, with moderate levels of adherence in both conditions associated with the strongest outcome relative to low or high levels of adherence.

Both Hogue et al. (2008) and Barber et al. (2006) conclude from their results that strict adherence may be detrimental to treatment outcomes and thus that flexibility should be utilized in

administering treatments. However, this may also reflect a more complex picture of the link between fidelity and outcome than captured by these studies. For example, flexible adaptation of a protocol component may facilitate a patient grasping a treatment concept or increase patient homework adherence; while other adaptations may diverge from treatment goals, such as delaying the use of an exposure-based intervention when a patient exhibits resistance. Thus consistency of adaptation with the larger treatment model may be critical to the success of flexibility. Strict adherence may result in attenuated patient receipt of the intervention in certain cases, and thus negatively impact fidelity. Overall, these studies imply mixed results in studies of fidelity in efficacy trials, with a more consistent positive association between fidelity and outcome in effectiveness and dissemination/implementation trials. In efficacy trials, the evaluation of the fidelity-outcome association may be hampered by a truncated range of scores achieved by a group of highly trained, closely supervised clinical providers implying a “ceiling effect.” Studies in which the fidelity-outcome association is evaluated within the context of an effectiveness or dissemination trial may provide a better test of this relationship given the greater likelihood for a wider or more representative range of fidelity scores. Indeed, a high level of integrity meeting efficacy trial standards for acceptable levels of adherence was noted in two studies in which an association between fidelity and outcome was not found (Huppert et al., 2001; Loeb et al., 2005). Moreover, this inconsistency in findings may be related to differences in the way in which fidelity is defined and assessed across studies. In particular, patient receipt of the intervention and adherence to procedures may be overlooked in some studies.

#### *Patient adherence and treatment outcome*

Another important component of treatment fidelity is patient adherence to the intervention. Indeed, homework compliance, a key component of patient adherence to cognitive-behavioral therapies was significantly associated with treatment outcome in a meta-analytic review (Kazantzis, Deane, & Ronan, 2000). This association has been repeatedly demonstrated in the treatment of anxiety, depression (see Kazantzis et al., 2000), and substance abuse, (e.g., Carroll, Nich, & Ball, 2005; Gonzalez, Schmitz, & DeLaune, 2006), among other conditions (e.g., Tolin, Frost, & Steketee, 2007). In a study of a computerized CBT program as an adjunct to treatment as usual for substance dependence (Carroll et al., 2008), homework completion and treatment involvement (including homework compliance and session attendance) were both strongly associated with outcome, with significant correlations in the magnitude of a large effect size ( $r = 0.77$  and  $r = 0.85$ , respectively). Moreover, in a study of the association between homework compliance and outcome in cognitive-behavioral therapy for depression, Burns and Spangler (2000) found support for a causal effect of compliance on clinical improvement. However, the assessment of homework compliance in clinical trials has been inconsistent, and often involves measuring compliance as only completion of homework, without consideration of quality (see Kazantzis, Deane, & Ronan, 2004).

Patient utilization of intervention components during both acute treatment and following treatment discontinuation are also important to the receipt of the intervention. In a study of components of a computerized cognitive-behavioral intervention for the prevention of eating disorders, the frequency of patient usage of elements such as accessing information and number of weeks of use predicted improvement in dietary restraint following the intervention (Manwaring et al., 2008). Moreover, a study of patient adherence to procedures following acute CBT for chronic pain

suggested that continued adherence was a robust predictor of long-term outcome (Curran, Williams, & Potts, 2009)

#### *Flexibility and treatment outcome*

Some have argued that adaptation from original formats is necessary to transport treatments to service provision settings; however, the way in which adaptation should occur is unclear. Kendall, Gosch, Furr, and Sood (2008) describe the concept of “flexibility within fidelity” identifying a distinction between flexible use of a treatment and poor adherence to a treatment. Their definition allows for adjustments to be made to protocol components based on relevant individual differences, such as developmental stage and cognitive ability. For example, in the treatment of panic disorder, when a patient reports that the exercises used for interoceptive exposure do not replicate the feared sensation, using a creative exercise to more closely replicate the target sensation (e.g., wearing earmuffs while spinning in a chair to increase feelings of disorientation/disconnectedness, drinking a caffeinated beverage before running stairs to replicate feeling “jittery”) or using relevant metaphors would represent flexible adaptations of the treatment that do not jeopardize adherence. Koerner, Dimeff, and Swenson (2007) suggest that flexibility within the context of the model is important in the implementation of Dialectical Behavior Therapy (DBT; Linehan, 1993). The authors also suggest that there are several risks to adaptation, including the potential loss of effectiveness; and emphasize that adherence to the treatment model be maintained in any setting-specific adaptation.

Several studies have evaluated the impact of flexibility on treatment outcome. In particular, studies evaluating the matching of patients to specific interventions have yielded mixed results. Indeed, there has been a recent move toward “personalized” care as a goal for mental health care (Insel, 2009). In a study of patient-matched behavioral couples therapy, acute outcome was similar for individualized and standard protocols, however, long-term outcome suggested additional benefits of the individualized program (Jacobson et al., 1989). Similar results have been noted in some studies of treatments targeted for particular patient characteristics (e.g., McKnight, Nelson, Hayes, & Jarrett, 1984; Ost, Jerremalm, & Johansson, 1981); however, other individualized protocols have demonstrated worse outcome relative to standard protocols (e.g., Schulte, Kunzel, Pepping, & Schute-Bahrenberg, 1992) or similar outcomes (e.g., Mersch, Emmelkamp, Bogels, & van der Sleen, 1989; Mersch, Emmelkamp, & Lips, 1991; Nelson-Gray, Herbert, Herbert, Sigmon, & Brannon, 1990). Project MATCH, a large multi-site trial examining the utility of matching treatment for alcohol dependence based on pre-treatment patient characteristics initially reported only an effect of patient matching to treatment as a function of initial psychiatric severity on outcome (Project MATCH, 1997); however further analyses suggested that certain patient characteristics may be associated with better outcome from certain treatments (Witkiewitz, van der Mass, Hufford, & Marlatt, 2007). Nevertheless, predictions about treatment matching were not associated with improved outcome in the UK Alcohol Treatment Trial (UKATT Research Team, 2008).

In a study of matching patients to receive treatment for comorbid diagnoses or the principal diagnosis alone, Craske et al. (2007) randomized patients to receive either CBT for panic disorder (PD), or CBT for PD with sessions targeting a comorbid anxiety or mood disorder. All patients received 12 sessions of group CBT for PD with some patients receiving additional individual sessions targeting PD and others with individual sessions targeting the most severe comorbid condition. Including treatment for the comorbid disorder did not improve treatment efficacy, and, in fact, resulted in poorer outcome for all disorders relative to CBT for PD alone.

However, this finding was preliminary in nature given the small sample size and the findings were less strong in intent-to-treat analyses.

Few studies of clinician-driven flexibility (i.e., not determined based on a priori matching criteria) have been conducted. Kendall and Chu (2000) reported that the level of flexible adaptation of a manualized treatment for child anxiety was not associated with outcome; it neither facilitated nor attenuated symptom change. Moreover, level of flexibility utilized was not associated with patient variables evaluated, such as principal diagnosis and socio-demographic factors. It is important to note that in this study, therapist adherence to the protocol was very strong, and thus flexibility was occurring within the confines of high treatment fidelity, creating, perhaps, once again a ceiling effect.

#### *The role of competence*

The ability to flexibly apply a treatment while remaining adherent may require a particularly advanced skill set. In a report describing a model of competence in the administration of CBT, Roth and Pilling (2007) describe “metacompetences” as the level of competence associated with an understanding of both theory and application and the ability to work flexibly and with adherence to adapt the model to the individual patient’s needs. This type of skill may be a difficult target of training and is particularly difficult to measure.

Indeed, as described above, the conceptual relationship between competence and fidelity lacks a clear consensus in the field. In particular, the development of a clear definition of competence that facilitates measurement has been lacking. For example, many measures of competence used in clinical trials have demonstrated particularly low inter-rater reliability and the strategies used for measuring competence in clinical trials vary widely (see Barber et al., 2007). Available data on the association between competence and outcomes suggest that, similar to the evidence for other fidelity studies, there is a weak or inconsistent association between competence and patient outcomes in efficacy studies (e.g., Barber et al., 2007; Shaw et al., 1999). Similar to the results for fidelity trials, these studies may be hampered by a restricted range of scores, thereby limiting the ability to detect an association between these variables.

Recently, several efforts have been made to better conceptualize competence in the service of improving its measurement and training. For example, Roth and Pilling (2007) reported the results of a workgroup commissioned by the Improving Access to Psychological Therapies program to define the competences needed to administer CBT for patients with anxiety and depression. This model uses a stepped approach that considers both higher and lower order competences and describes skills in sufficient detail to facilitate its use as a model for training and assessment. Similar efforts to define competence are underway (e.g., American Psychological Association Task Force on the Assessment of Competence in Professional Psychology; Kaslow et al., 2007). The development of clearly defined markers of competence will be important for the development of training and assessment models for dissemination and implementation efforts, and may be a key element to achieving flexible adherence in treatment administration.

#### **Transdiagnostic, modular, and principle-based treatments**

At this time, the associations among fidelity, flexible adaptation, and treatment outcome remain unclear given the mixed findings reported above. However, based on the available literature, particularly in transporting treatments to service provision

settings, fidelity (by both therapist and patient) appears to be a strong predictor of treatment outcome. Moreover, preliminary evaluations of fidelity suggest that when adherence is maintained, flexibility does not attenuate treatment outcome, suggesting that it may be possible to utilize adaptations (which may facilitate dissemination) while still maintaining treatment adherence. The recent development of transdiagnostic treatment protocols may provide a particularly promising opportunity to achieve this balance of fidelity and flexibility.

In recent years several treatments have been developed that diverge from the single-disorder focus of traditional manualized interventions. This work stems from advances in understanding of the nature of psychopathology and the processes that are applicable across disorders (e.g., common emotional processes). Moreover, proponents of this approach emphasize the potential for facilitated dissemination with a transdiagnostic treatment relative to training in multiple single-disorder interventions. The treatments developed to date can be broadly characterized as transdiagnostic, modular, and principle-based interventions. This discussion will not include treatments targeting commonly co-occurring disorders (e.g., bipolar disorder and substance dependence; Weiss et al., 2007) and will instead focus on treatments designed for broader applicability across several disorders.

#### *Transdiagnostic treatments*

The rationale for transdiagnostic treatments has focused on the similarities among disorders, particularly those in a similar class of diagnoses, those with overlapping clinical features, or those with high levels of co-occurrence or common maintaining mechanisms. Given their substantial overlap and elevated comorbidity, emotional disorders generally, and anxiety disorders in particular have been the largest area of research interest to date. Indeed, cognitive-behavioral treatments for each of the anxiety disorders are very similar and typically include the same core components (e.g., cognitive restructuring, in vivo exposure).

Barlow and colleagues (Allen, McHugh, & Barlow, 2008; Barlow, Allen, & Choate, 2004) developed a unified treatment protocol for emotional disorders, characterized as unipolar mood and anxiety disorders (with potential applications to other disorders). The development of the unified protocol was motivated by research indicating similarities across the emotional disorders, including presence of common characteristics among disorders (e.g., Brown, 2007; Brown, Chorpita, & Barlow, 1998), high rates of comorbidity (e.g., Kessler, Chiu, Demler, Merikangas, & Walters, 2005), and improved outcomes for comorbid conditions when treating a principal disorder (e.g., Borkovec, Abel, & Newman, 1995; Brown & Barlow, 1995; Craske et al., 2007). The most recent iteration of the unified protocol utilizes a modular format in which the “dose” of each component of the intervention can be altered based on idiographic presentations (Barlow et al., 2008). The unified protocol is an exposure-based cognitive-behavioral treatment that focuses on changing maladaptive responding to emotional experiences. Adapting common components of CBT for emotional disorders (e.g., cognitive reappraisal) and building upon the latest advances in emotion science, this treatment attempts to target the core processes underlying emotional disorders. The unified protocol is currently being evaluated, however, preliminary results have been very promising, with results in the range of large effect sizes across disorders ( $d = 1.94$ ), and ranging from  $d = 1.70$  for generalized anxiety disorder to  $d = 3.13$  for obsessive compulsive-disorder (Ellard, Fairholme, Boisseau, Farchione, & Barlow, 2009). These effect sizes are comparable to or exceed the effect sizes noted for single-disorder treatments (see Butler, Chapman, Forman, & Beck, 2006; Hofmann & Smits, 2008).

Similar interventions have been developed for utilization across the anxiety disorders, many utilizing a group format (e.g., Erickson, 2003; Norton & Hope, 2005), which are in relatively early stages of development and evaluation. A recent preliminary meta-analysis of 8 efficacy trials evaluating transdiagnostic treatments for anxiety disorders supported the efficacy of this approach with effect sizes ranging from moderate to large ( $d$  ranged from 0.37 to 2.66) and a large effect size ( $d = 1.29$ ) when collapsing across studies. This also compares favorably to recent meta-analyses of CBT for anxiety disorders that have similarly found moderate to large effect sizes for disorder-specific interventions (e.g., Hofmann & Smits, 2008; Norton & Price, 2007).

Another transdiagnostic treatment for the anxiety disorders has been developed for use in primary care and involves the patient's primary care physician along with other providers (Sullivan et al., 2007). The collaborative care model, which has demonstrated successful application to both depression (Unützer et al., 2002) and panic disorder (Roy-Byrne et al., 2005), is currently being tested as a treatment for common anxiety disorders (panic disorder, generalized anxiety disorder, social phobia, and posttraumatic stress disorder). Within this model, patients identified with an anxiety disorder receive either front-line pharmacologic (selective serotonin reuptake inhibitor) or cognitive-behavioral treatment. In CBT sessions, the treatment targets the most severe diagnosis, however, clinicians are trained generally in CBT for the anxiety disorders as well as in strategies to modify CBT for each of the four target disorders; thus, instead of training in four distinct protocols, clinicians receive training in how to adapt CBT skills for each specific diagnosis. Additionally, a computer-based CBT intervention, also designed for application across the anxiety disorders, is used as an adjunctive treatment and has demonstrated preliminary feasibility, tolerability, and efficacy (Craske et al., 2009).

The prevalence of eating disorders is characterized by a particularly large number of “not otherwise specified” (NOS) diagnoses that reflect clinical presentations with mixed features of extant eating disorders (see Fairburn et al., 2007). Given the overlapping features of these disorders and the elevated prevalence of NOS diagnoses, Fairburn et al. (2009) developed a cognitive-behavioral treatment for patients with eating disorders adapted from the treatment of bulimia nervosa that can be used across the full range of presentations. Cognitive Behavioral Therapy-Enhanced (CBT-E) consists of 20 sessions involving interventions targeting common processes across the eating disorders (e.g., binge eating, concern about weight). Data from a large randomized controlled trial suggest that CBT-E is an efficacious treatment for eating disorders, with strong treatment effects relative to waitlist control (Fairburn et al., 2009).

#### *Modular treatments*

Modular treatment approaches balance the structure of treatment, including maintaining fidelity to conceptual and theoretical principles with flexibility in applying core strategies based on individual clinical presentations, psychosocial functioning, and identified treatment targets. Many manualized treatments are moving toward a more flexible application, emphasizing flexibility in pacing the treatment to reflect individual differences, such as motivation and severity of pathology (e.g., Henin, Otto, & Reilly-Harrington, 2001). For example, the Craske and Barlow (2007) treatment manual *Mastery of Your Anxiety and Panic*, guides the clinician to pace progress in applying the treatment components based on the individual's specific needs. More novel modular treatments, which include flexibility in the order or inclusion of modules, have been developed for disorders known for heterogeneous clinical

presentations including child anxiety disorders (Chorpita, 2007) and psychotic disorders (Addington & Gleeson, 2005; Cather et al., 2005).

Clinical presentations of anxiety disorders in children vary substantially, however symptoms are often related to the same underlying pathological processes (see Chorpita, 2007). Modular Cognitive-Behavioral Therapy for Childhood Anxiety Disorders (Chorpita, 2007) was developed to systematically target these common processes (e.g., negative affect) utilizing a flexible modular approach based on case formulation. This treatment incorporates components of ESTs (e.g., exposure) and has demonstrated efficacy in a pilot investigation, with clinically significant improvement through 6-month follow-up (Chorpita, Taylor, Francis, Moffitt, & Austin, 2004). In this treatment, four core modules are recommended for all patients, including psychoeducation, self-monitoring, exposure, and relapse prevention. Supplemental modules such as using rewards, cognitive restructuring, and social skills training can then be added at the clinician's discretion to address the presenting symptoms. In addition to allowing for flexibility in the administration of modules, the treatment emphasizes individualization of the presentation of the treatment by selecting metaphors, examples, and style of language based on the fit to the patient.

Given schizophrenia's complex clinical presentation, modular treatment approaches have been developed for first episode psychosis (Addington & Gleeson, 2005) as well as for refractory symptoms of schizophrenia (Cather et al., 2005). For example, Functional CBT (fCBT), a treatment designed for patients with schizophrenia spectrum disorders, consists of a core five sessions, after which remaining sessions utilize specified decision rules (based on the presenting symptoms) to select the interventions that best fit the patient's goals. A pilot study (Cather et al., 2005) found that fCBT was well tolerated and resulted in improvement in positive symptoms.

#### *Principle/component-based treatments*

As a proliferation of treatments has occurred in the field, the benefit of a movement toward treatments based on known "active ingredients" has gained support. The most advanced example of this approach is the "common elements" approach, which was motivated by the acknowledgement of the large number of available treatments for children and the difficulty inherent in selecting appropriate interventions (e.g., Chorpita, Becker, & Daleiden, 2007). This approach, also termed the "distillation and matching model" (DMM) extrapolated from the empirical literature to identify components commonly utilized across protocols to reduce a large number of treatments to a common set of treatment principles (see Chorpita & Daleiden, 2009). These principles could further be matched to specific patients based on the available evidence for their use in patients with similar characteristics (e.g., gender, diagnosis). The efforts by this group have resulted in the identification of common practice elements for a number of clinical presentations among children and adolescents (Chorpita & Daleiden, 2007). The implementation of this model in the state system of care in Hawaii recently began and evaluation of its efficacy is ongoing.

#### *Fidelity, adaptation, and the future of transdiagnostic treatments*

Although results are preliminary in nature and much research remains to determine whether transdiagnostic treatment modalities are efficacious and effective for the treatment of psychological disorders, results to date are very promising. Relative to the problem of balancing fidelity and adaptation, these treatments provide a particularly conducive strategy to allowing for adaptation

of interventions based on the setting and individual patient, while also delineating treatment components (and at times decision rules) to allow for the treatment to be replicated reliably. Thus, through providing a more flexible design that no longer requires slavish adherence to treatment components in a strict order and timeline, more flexible transdiagnostic treatments may shift the relevant variable to the degree of skill or competence with which components are administered. Moreover, these interventions are consistent with the movement toward "personalized" mental health care (see Insel, 2009).

In addition to providing a modality that may facilitate both adaptation and fidelity, transdiagnostic treatments may present substantial cost advantages relative to disseminating single-disorder treatments. For example, even at specialty outpatient clinical service settings, clinicians would need to receive training in multiple individual protocols to be able to treat the target patient population using ESTs. A community mental health center that serves a wider variety of clinical presentations would require training in even more protocols. Attempting to maintain fidelity to each of these individual treatments would present an enormous challenge to a clinical care system. Given the cost of didactic (e.g., workshop, written materials) and competence (e.g., supervision and feedback) training, implementing multiple treatments to a facility is often not a feasible consideration. Transdiagnostic protocols offer a drastically reduced number of necessary trainings and thus have the potential to result in substantial cost savings relative to single-disorder treatments. Moreover, given the potential threat to outcomes of *not* including competency-based training and fidelity monitoring and feedback, these cost savings may allow for more intensive training in one treatment and thus greater outcome improvements.

#### **Discussion**

Among the considerations for the successful dissemination of ESTs, the degree to which treatments tested in controlled research designs will achieve similar outcome benefits in clinical service provision settings is of particular importance. The central role of treatment fidelity in studies of treatment efficacy has been emphasized; however, the degree to which ESTs are replicated in practice settings has been inconsistent. Moreover, adaptation is a natural occurrence of dissemination and may enhance the adoption and maintenance of treatment implementation.

This paper reviewed the available literature regarding the associations between treatment fidelity, flexibility, and outcome to provide a perspective on the relative importance of these factors. Although studies are limited by variability in how fidelity is defined and assessed, fidelity appears to be an important factor in the transportability of treatments from research to service provision settings, and may be responsible for the loss of efficacy that can be seen in these settings. Indeed, qualitative feedback from training initiatives indicates that clinicians intend to use "components" of ESTs in future work (e.g., Markman et al., 2004); the degree to which partial implementation may attenuate efficacy is unclear. Despite the apparent importance of fidelity, adaptation may be both necessary to the transfer of treatments and may also facilitate adoption. Given the evidence to date regarding training in ESTs, there is no indication at this time to suggest that successful implementation is possible in the absence of some form of supervision, consultation, and/or fidelity monitoring.

The recent introduction of transdiagnostic and principle-based treatments may represent a shift in the way that fidelity is conceptualized. Indeed, if flexibility can be achieved while maintaining fidelity to the treatment model, the benefits of both adherence and adaptation may be realized. Weisz, Donenberg, Han,

and Weiss (1995) emphasized that in the case of more modest outcomes in the implementation of ESTs in service provision settings that treatment developers should consider changes to clinical interventions to allow them to be more transportable. The movement toward more flexible treatment protocols that maintain the specificity necessary for replication may provide the next revolution in the treatment of psychological disorders.

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