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Posttraumatic Stress Disorder Treatment Outcome Research: The Study of Unrepresentative Samples?

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The authors review sample composition and enrollment data for 34 studies cited in the International Society for Traumatic Stress Studies (ISTSS) 2000 Practice Guidelines as meeting the Level A U.S. Agency for Health Care Policy and Research (AHCPR) classification for treatment of adult posttraumatic stress disorder (PTSD), and compare data from more recent research. Findings reveal that many published reports omitted vital data including exclusion criteria and rates, demographics, and trauma exposure history. Moreover, severe comorbid psychopathology, a common feature of treatment-seeking individuals with PTSD, emerged as the predominant reason for exclusion across studies. Subsequently published studies exhibited improved reporting of sample characteristics and demonstrated comparable outcomes despite inclusion of more diverse trauma exposure samples. Findings indicate the need for future efficacy research to adopt more comprehensive reporting requirements and to test the applicability of validated treatments to individuals suffering from as yet unstudied combinations of PTSD and prevalent comorbid disorders.

Major strides have been made over the past 15 years in posttraumatic stress disorder (PTSD) treatment outcome research, due to the sustained efforts of dedicated research scholars and scientist practitioners in this field. Several empirically supported, symptom-based, manualized interventions have been developed and tested in controlled research settings, and replications studies have established their efficacy in treatment of PTSD (Foa, Keane, & Friedman, 2000). As a result, practice guidelines for PTSD treatment have been established (Foa et al., 2000).

During the 17th Annual Meeting of the International Society for Traumatic Stress Studies, a symposium was organized around scientific comparison of some of the leading interventions for PTSD (Foa, 2001): prolonged exposure (PE), cognitive processing therapy, cognitive restructuring, and eye-movement desensitization and reprocessing (EMDR). In addition to the interventions described in this symposium, other treatments for PTSD identified to date from well-controlled efficacy studies include stress inoculation training (Foa et al., 1999; Foa, Rothbaum, Riggs, & Murdock, 1991) and pharmacotherapy with selective serotonin reuptake inhibitors and tricyclic antidepressants (Foa et al., 2000).

Based on these advances in the treatment of posttraumatic stress, Dr. Keane's discussion at this symposium anticipated the next phase in the evolution of PTSD outcome research: the use of clinical effectiveness trials to evaluate the application of identified treatments within naturalistic community practice settings (Keane, 2001). This discussion echoed the increased recognition in the mental health field of the importance of external validity in treatment outcome research, as an exclusive focus on intervention efficacy often fails to capture the complexities of clinical practice (Beutler, 1998; Persons & Silberschatz, 1998; Howard, Moras, Brill, Matinovich, & Lutz, 1996). Specifically, once an intervention has been

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found to demonstrate *efficacy* (i.e., desired postintervention outcomes in experiments applying rigorous control over such variables as treatment setting, subject selection and randomization, clinician training, intervention implementation, and collection and analysis of data), the next, and more critical, question concerns its *effectiveness* (i.e., the ability of this intervention to transport well to clinical practice and achieve comparable postintervention outcomes once experimental controls on setting, subject, and clinician characteristics are removed. Effectiveness research is needed to address such questions as whether empirically validated treatments for PTSD can be reliably taught to practitioners, well tolerated by consumers, and readily adapted to the varying treatment needs of diverse treatment populations across a range of clinical practice settings.

However, before the focus of the traumatic stress field shifts in the direction of effectiveness research, it may be time to pause and consider some of the assumptions implicit in the PTSD treatment efficacy research conducted to date. Although we now maintain we know "what works" for PTSD, have we adequately addressed the question of "for whom" these treatments actually work? Specifically, has the extant body of well-controlled efficacy research been conducted on representative samples of traumatized people suffering from PTSD, or has it been a study of restricted samples?

Comorbidity and Posttraumatic Stress Disorder

There is perhaps no other Axis I disorder for which the issue of comorbidity is more relevant than PTSD. The convergence of leading epidemiological data clearly indicates that PTSD rarely occurs alone, and has routine comorbidity rates of 80% (Breslau, Davis, Andreski, & Peterson, 1991; Kessler, Sonnega, Bromet, Hughes, & Nelson, 1995; Solomon & Davidson, 1997). A consensus statement released by leaders in the field of psychological trauma concluded that simple or "pure" PTSD is unrepresentative of the typical presentation of treatment-seeking individuals with trauma histories (Ballenger et al., 2000).

Comorbid conditions are, however, among the most frequent exclusion criteria for participation in PTSD efficacy research. The pivotal question, then, becomes whether PTSD efficacy research tends to exclude potential participants based on conditions highly comorbid with PTSD, thereby threatening the external validity of study findings through the creation of artificial homogeneity in experimental PTSD samples. In such instances, as research on other Axis I disorders has demonstrated, the more common the occurrence of excluded comorbid disorders, the more likely findings from treatment efficacy research would be of limited generalizability to typical individuals presenting with the target disorder in clinical practice (e.g., Westen & Morrison, 2001).

Large-scale epidemiological research has established that the disorders most consistently and highly comorbid with PTSD include major depression (37–48%), alcohol abuse/dependence (28–52%), substance abuse/dependence (21–35%), simple phobia (29–31%), social phobia (28%), and agoraphobia (16–22%; Breslau et al., 1991; Jacobsen, Southwick, & Kosten, 2001; Kessler et al., 1995). Likewise, the risk for suicidal ideation and behavior has been found to be significantly greater in individuals with PSTD than for any other anxiety disorder (Ballenger et al., 2000). In a large-scale community study, suicide attempts were reported by 20% of individuals with PTSD, as compared with 4% of individuals with other diagnoses and 1% of those without psychiatric diagnoses. Those with PTSD were 14.9 times more likely to have made a suicide attempt; even when controlling for comorbid depression, individuals with PTSD remained 8.2 times more likely to attempt suicide than those without PTSD (Davidson, Hughes, Blazer, & George, 1991). Other highly comorbid disorders have either been less routinely measured (obsessive-compulsive disorder [OCD]: 15%; Breslau et al., 1991) or vary more markedly by gender (conduct disorder: 43% in men vs. 15% in women; Kessler et al., 1995).

While rates of comorbidity of bipolar disorder in community samples with PTSD have been found to be more modest (5–12%), the prevalence of this disorder has been found to be significantly higher among individuals with PTSD than in the general population ($\approx$1% estimated population prevalence; Breslau et al., 1991; Kessler et al., 1995). Prevalence of mania is also significantly higher among clinical samples with than without PTSD (i.e., 18% vs. 3%; McFarlane, Bookless, & Air, 2001). In fact, odds ratios for diagnosis of bipolar disorder are consistently among the top four for comorbid disorders with PTSD (i.e., Breslau et al., 1991; Kessler et al., 1995).

To date, no large-scale epidemiological research has assessed the prevalence of comorbid psychotic disorders in community samples with PTSD. However, a growing body of research on trauma exposure and PTSD in clinical populations with schizophrenia and other severe mental illness has indicated a significant relationship among these disorders. Research indicates significantly higher prevalence of trauma exposure and PTSD among individuals with psychosis than among the general population (Mueser et al., 1998; Resnick, Bond, & Mueser, 2003). Odds ratios for the presence of schizophrenia or schizophreniform disorder among individuals with versus

without PTSD are marked (ranging from 10.30 to 37.07), and psychosis is consistently one of the top two comorbid disorders when included in analyses (Davidson et al., 1991; McFarlane et al., 2001).

These comorbidity figures place two opposing realities in stark contrast: (a) PTSD shows rapid response to brief, manual-driven and symptom-based protocols; and (b) many trauma victims who develop PTSD also exhibit comorbid disorders, many of which are highly treatment resistant. Accordingly, true advancement of the field will require a deliberate process of evaluation and adaptation of efficacious treatments with less restricted, more clinically representative PTSD samples.

Impact of Exclusion and Attrition on Conclusions of Treatment Efficacy Research

Exclusion

A prominent feature of efficacy research is stringent control of variables. Among the more commonly employed methods of control is the use of carefully defined inclusion and exclusion criteria to maximize internal validity. However, this increase in internal validity may occur at the cost of a loss in external validity, as study findings may not be applicable to clinical practice samples that are more broadly defined (Sullivan & Joyce, 1994). While stringent inclusion and exclusion criteria are hallmark features of most efficacy research, investigators of various Axis I disorders have noted that participants screened out of efficacy studies may in fact be distinguished by symptom severity, comorbid conditions, and demographic characteristics representative of typical treatment-seeking individuals with these disorders (Humphreys & Weisner, 2000; Persons & Silberschatz, 1998; Sullivan & Joyce, 1994). Similarly, in applying exclusionary criteria recommended by Litz, Blake, Gerardi, and Keane (1990) to a Veterans Administration Medical Center (VAMC) outpatient sample, Frueh, Mirabella, and Turner (1995) found that 73% of patients with PTSD would have met criteria that deemed them "unsuitable" for the use of exposure therapy, a modality identified as highly efficacious in treatment of combat-related PTSD.

Attrition

The external validity of treatment efficacy research can also be affected by attrition of research participants. Subject attrition can occur during study enrollment and pretreatment evaluation, following treatment randomization, or during treatment. The impact on study validity of *pretreatment attrition,* or the refusal to participate by potentially eligible participants, has yet to be studied in PTSD outcome research. Efficacy research on other Axis I disorders has revealed self-selection patterns in study enrollment (e.g., differential refusal of medication vs. psychotherapy treatment conditions) that may limit generalization of study findings (Hofmann et al., 1998). Implications for the external validity of PTSD outcome research comparing pharmacotherapy to psychotherapy are addressed below in examination of pretreatment attrition data from the first randomized clinical trial (RCT) of this kind.

More is known about attrition following treatment randomization in PTSD efficacy research. Rates of treatment attrition, or dropout, in these studies range from 14% (psychological therapies) to 32% (drug therapies; Van Etten & Taylor, 1998) and are consistent with reported rates for other clinical populations (Wierzbicki & Pekarik, 1993). However, in the few studies attempting to treat PTSD in conjunction with comorbid disorders, the dropout rate rises considerably. For instance, in their intervention for PTSD plus substance dependence, Najavits, Weiss, Shaw, and Muenz (1998) reported dropout rates of 37% based on a definition of treatment *completers* as those completing at least 25% of sessions. However, less than half of the participants completed all sessions. Brady, Dansky, Back, Foa, and Carroll (2001) reported an even higher noncompleter rate (62%) in their dual-diagnosis PTSD treatment study, even though their study also employed a liberal definition of completion (i.e., 10 of 16 sessions).

Demographic and baseline severity characteristics of dropouts are not consistently included in the results of treatment outcome studies. When such data are provided, they often reveal significant differences between treatment completers and dropouts, adding to concerns about the generalizability of study findings to those populations less able to maintain treatment enrollment (Wierzbicki & Pekarik, 1993). In studies specifically examining retention in PTSD efficacy research, factors found to discriminate dropouts versus completers have included higher post-rape symptomatology, unemployment, lower socioeconomic status (SES; Foa et al., 1991), or more severe baseline personality pathology (Fisher, Winne, & Ley, 1993; Munley, Bains, Frazee, & Schwartz, 1994).

A Review of Gold Standard Posttraumatic Stress Disorder Treatment Outcome Research

To assess these concerns about the generalizability of PTSD treatment efficacy research in a comprehensive

and empirical manner, we examined study enrollment and sample characteristics for the set of gold standard adult treatment outcome trials that form the basis of the 2000 ISTSS (International Society for Traumatic Stress Studies) Practice Guidelines for the Effective Treatment of PTSD (Foa et al., 2000). We then compared findings of our review to data from more recently published PTSD efficacy trials, as well as from our own research, in an effort to address questions left unanswered in the ISTSS Practice Guideline studies' reporting of this information and to identify continued advances in this field of research.

This review included all treatment outcome studies cited in these guidelines as having met the U.S. Agency for Health Care Policy and Research (AHCPR) Level A rating, along with all pharmacotherapy studies included in the guidelines that employed a randomized clinical trial design (Foa et al., 2000). Studies delineated as Level A were judged to be "very well-controlled," "methodologically rigorous," and to meet all or most of the gold standards delineated by the AHCPR: clearly defined target symptoms; reliable and valid measures; blind evaluators; assessor training; manualized, replicable, specific treatment programs; unbiased/random assignment to treatment; and treatment adherence.

Based on these criteria, 34 studies were identified for review. Of these, 14 studies were classified as cognitive–behavioral, 7 as EMDR, 11 as pharmacotherapy, and 2 as group therapy. One study (Brom, Kleber, & Defares, 1989) compared cognitive–behavioral, hypnotic, and psychodynamic therapies, and was subsumed within the cognitive–behavioral category in this review. Our review examined four specific features of these studies: (a) the extent to which studies reported attrition, exclusion, and sample composition data; (b) rates of attrition and exclusion in studies reporting this information; (c) reasons for exclusion; and (d) breadth of sample composition.

Reporting of Study Enrollment Data

Reporting of exclusion and attrition data was examined at three phases of efficacy trials: initial screening, pretreatment assessment, and treatment (see Table 1). Findings revealed that the majority of studies reported only partial information; of 34 studies reviewed, less than half ($n = 11$) reported pretreatment exclusion and attrition data, and only two studies (Tarrier et al., 1999; Wilson, Becker, & Tinker, 1995) provided initial screening data. Surprisingly, three studies neglected to report the number of participants randomized into treatment, citing only the final number of study completers and preventing complete estimation of treatment dropout rates.

Rates of Reported Exclusion and Attrition

Combined information from 31 studies reporting this information revealed that 80% of randomized participants completed the full protocol. Comparable rates of completion were observed across psychotherapy studies (81–92%), with lower rates of completion reported in medication trials (69%). While an 80% completion rate is substantial, this figure does not account for loss of enrolled study participants due to either *pretreatment*

Table 1. Enrollment Data Reported in ISTSS Practice Guidelines (2000) Gold Standard PTSD Efficacy Trials ($N = 34$)

	Data from 2 studies[a]	Data from 11 studies[a]	Data from 31 studies[a]
Phase One: Screening			
Total participants screened (N)	368		
Excluded (n)	Incomplete data		
Study refusal (n)	Incomplete data		
Phase Two: Pretreatment Assessment			
Total participants assessed (N)	241	1,101	
Excluded (n)	Incomplete data	175	
Dropouts (n)	Incomplete data	232	
Phase Three: Treatment			
Total participants randomized (N)	152	694	1,808
Treatment dropouts (n)	10	107	359
Treatment completers (n)	142	587	1,449
% Total potential study participant pool represented among treatment completers	39%	53%	80%

[a]Data included from studies reporting complete enrollment information for a given phase of treatment outcome research.

attrition or exclusion. As such, consideration of completion rates alone affords an incomplete appraisal of subject flow in that it does not account for the enrollment outcomes of all individuals meeting initial study inclusion criteria for PTSD. When these outcomes were assessed for the 11 studies reporting pretreatment enrollment data, it was found that 21% of participants dropped out prior to starting treatment, and an additional 16% were eliminated at baseline due to the presence of exclusionary criteria. Thus, only 63% of enrolled study participants were randomized into treatment across these studies, with approximately half (53%) of the full set of enrolled study participants completing treatment.

Data from the two studies reporting information for all three phases (screening, assessment, and treatment) yielded a combined total of 35% of potential participants who were screened out prior to pretreatment assessment. This percentage represents individuals who were screened out due to not meeting inclusion criteria or meeting exclusion criteria, as well as individuals who self-selected out of the study. In these two studies, less than half (41%) of all potential participants screened were ultimately randomized into treatment, with a similar proportion (39%) of the full set of screened individuals completing treatment.

Criteria for Study Exclusion

Of 34 studies reviewed, 30 provided specific information about exclusion criteria; four studies did not delineate which, if any, exclusion criteria were utilized. Twenty exclusion criteria were employed across these studies, with seven used by at least 25% of studies (see Table 2). Five of the most common criteria excluding potential participants related to the presence of comorbid or severe pathology, with the remaining two concerned with medical problems or past or concurrent use of psychotropic medication. It is noteworthy that the latter two criteria are often a proxy for more complex adaptation to chronic trauma exposure (e.g., Andreski, Chilcoat, & Breslau, 1998). Notably, several of these reasons for exclusion involve the presence of disorders (alcohol or substance abuse/dependence) or manifestations of behavioral disturbance (suicidal ideation) that as described above have been identified to co-occur with high regularity in typical individuals with PTSD. Other top reasons for exclusion (psychosis, severe psychopathology including bipolar disorder) represent disorders that occur less frequently across clinical and community samples, but for which individuals with PTSD have been demonstrated to be at elevated risk.

Table 2. Exclusion Criteria Across ISTSS Practice Guidelines (2000) Gold Standard PTSD Efficacy Trials (Reporting This Information ($n = 30$))

Exclusion criteria	Number of studies employing criterion	%
Treatment issues		
Medical problems	11	36.7
Medication use (past and/or concurrent)	11	36.7
Concurrent PTSD treatment	5	16.7
Medication hypersensitivity or previous lack of response	3	10.0
Head injury	2	6.7
Insufficient English	2	6.7
Past PTSD treatment	1	3.3
Study interfering issues		
Trauma-related litigation or disability	3	10.0
Ongoing abuse	2	6.7
Question about participant motivation or reliability of report	2	6.7
Study specific design confounds		
Assault by family member	2	6.7
POW experience	1	3.3
Unclear military background	1	3.3
Psychiatric/comorbidity		
Psychosis	23	76.7
Alcohol/substance use-related issues	20	66.7
Severe psychopathology (unspecified or other including bipolar disorder)	17	56.7
Organic mental disorder	14	46.7
Suicidal ideation	8	26.7
Dissociative disorder	4	13.3
Aggression	1	3.3

Sample Characteristics

Key demographic information was examined across studies (see Table 3). Two main points emerged from this examination: (a) reporting of demographic information is insufficient in many areas; and (b) some trauma populations appear to be underrepresented within the PTSD efficacy literature. About the reporting of demographic information, the extent of reporting varied by type of information and type of study. Across studies, reporting was best for age (97% of studies reporting) and gender (91%), and worst for socioeconomic status (35%), and education level (44%). Reporting of demographic information within pharmacotherapy studies was of particular concern: Of 11 studies reviewed, only 2 described their sample in terms of racial or ethnic background, and only 1 included information regarding socioeconomic status or education level. Inclusion of comprehensive sample demographics in published reports is critical to interpretation of PTSD outcome research, as these variables have been linked not only to treatment dropout but also to treatment-seeking behaviors and use of mental health services (Koenen, Goodwin, Struening, Hellman, & Guardino, 2003).

Table 3. Demographic Information Reported for ISTSS Practice Guidelines (2000) Gold Standard PTSD Efficacy Studies

Study authors and year	Sample[a]	Age[b]	% Female	% Minority	Includes SES[d]	Includes education
Cognitive–behavioral therapy studies						
Boudewyns & Hyer (1990)	1	39; NR[c]	0	21	Y	Y
Brom, Kleber, & Defares (1989)	4	42; 18–73	79	NR	Y	Y
Cooper & Clum (1989)	1	37; NR	0	14[c]	N	N
Echeburua et al. (1996)	2	22; 15–45	100	NR	N	Y
Echeburua et al. (1997)	2	20; 15–41	100	NR	N	Y
Foa et al. (1999)	2	35; NR	100	36	Y	Y
Foa, Hearst-Ikeda, & Perry (1995)	2	33; NR	100	40	N	N
Foa et al. (1991)	2	32; NR	100	27	Y	N
Keane et al. (1989)	1	35; NR	0	19	N	Y
Marks et al. (1998)	4	38; NR	36	NR	Y	N
Peniston & Kulkosky (1991)	1	37; NR	0	NR	N	N
Silver, Brooks, & Obenchain (1995)	5	46; NR	0	NR	N	N
Tarrier et al. (1999)	4	39; NR	42	NR	Y	Y
Watson et al. (1997)	1	46; NR	0	14	N	Y
EMDR studies						
Carlson et al. (1998)	5	48; 41–70	0	46	Y	N
Jensen (1994)	1	43; 40–55	0	NR	Y	Y
Marcus, Marquis, & Sakai (1997)	4	41; 18–73	79	34	N	N
Rothbaum (1997)	2	34; NR[c]	100	NR	Y	Y
Scheck, Schaeffer, & Gillette (1998)	4	21; 16–25	100	38	N	Y
Vaughan et al. (1994)	4	32; 20–78	64	NR	N	N
Wilson et al. (1995)	4	39; 21–63	50	4	Y	Y
Pharmacotherapy studies						
Baker et al. (1995)	4	44; 23–73	NR	NR	N	N
Brady et al. (2000)	4	40; 18–69	73	16	N	N
Braun et al. (1990)	4	38; 19–56[c]	NR	NR	N	N
Davidson et al. (1990)	5	NR	0	NR	N	N
Davidson et al. (1997/2001)[e]	4	37; 18–69	78	16	N	N
Kaplan et al. (1996)	4	40; 25–56	38	NR	Y	Y
Katz et al. (1995)	4	NR; 22–62	24	NR	N	N
Kosten et al. (1991)	1	39; NR	0	13	N	N
Reist et al. (1989)	5	38; 28–64	0	NR	N	N
Shestatzky et al. (1988)	4	39; 26–50[c]	NR	NR	N	N
van der Kolk et al. (1994)	4	40; NR	34	NR	N	N
Group therapy studies						
Alexander et al. (1989)	6	36; 23–55	100	24	N	Y
Zlotnick et al. (1997)	6	39; NR	100	2	Y	Y
Selected PTSD efficacy studies completed since publication of ISTSS 2000						
Cloitre et al. (2002)	6	34; NR	100	54	Y	Y
Kubany et al. (2004)	2	42; 18–70	100	47	N	Y
Resick et al. (2002)	2	32; NR	100	29	N	N
Taylor et al. (2003)	4	37; NR	75	23	Y	Y

Note. Full citations available in reference section of this paper when cited in text, all others as cited in Foa, Keane, Friedman, 2000. For all columns, Y = Yes, N = No, NR = Not reported.

[a]Sample: 1 = Vietnam veterans; 2 = Female assault/domestic violence; 3 = Motor vehicle accident; 4 = Unspecified or mixed PTSD; 5 = Veterans, unspecified or mixed; 6 = Child onset trauma. [b]Participant mean age and sample age range. [c]Numbers provided for completers only. [d]Socioeconomic status (SES) information considered included if study provided any of the following: income, current employment status, or occupation. [e]Davidson et al. (1997) included in treatment guidelines based on abstract of the American College of Neuropsychopharmacology 6th Annual Meeting, San Juan, Puerto Rico; full report published in Davidson, Rothbaum, Van der Kolk, Sikes, and Farfel (2001).

Notably, less than half (47%) of all studies specifically reported racial or ethnic background of participants, preventing definitive calculation of minority representation in this research. Nevertheless, in the 16 studies that did report this information, minority representation appeared low when compared against U.S. Census Bureau national estimates (U.S. Census Bureau, 2001): Specifically, only 6 studies (18% of all studies reviewed) included at least 25% minority participants. Inclusion of minority participants was particularly limited in pharmacotherapy trials of PTSD, in which not one study reported representative proportions of minorities. Moreover, even in the subset of

psychotherapy studies containing representative numbers of minority participants, the small sample sizes characteristic of this research limit thorough examination of group differences in responsivity to the various empirically supported treatments for PTSD. Clearly, more work needs to be done in this area.

Type of trauma exposure across samples was also found to be limited, with 27 (79%) studies targeting PTSD associated with adult-onset trauma exposure (e.g., sexual assault, combat experience, vehicular accident). While no studies in the ISTSS Practice Guidelines specifically excluded participants based on childhood-onset trauma history, the majority of studies targeting PTSD associated with adult onset trauma exposure either neglected to assess or report the presence of childhood onset trauma. Eight studies (24%) targeted PTSD samples with mixed or unspecified trauma history, including childhood maltreatment. Only two studies specifically targeted PTSD in adult survivors of childhood onset trauma. Both involved group treatment for adult survivors of childhood sexual abuse. No studies in the ISTSS Practice Guidelines focused on treatment of adult PTSD associated with other childhood-onset trauma exposures such as physical abuse, life-threatening medical illness, or witnessing domestic violence.

PTSD Efficacy Research Published Since the ISTSS Practice Guidelines

Since release of the ISTSS Practice Guidelines, several additional PTSD efficacy trials meeting gold standard criteria have been published. Some of these studies have demonstrated the applicability of several treatments identified in the ISTSS guidelines to a broader spectrum of trauma exposure populations (e.g., Kubany et al., 2004; Resick, Nishith, Weaver, Astin, & Feuer, 2002; Taylor, Thordarson, Maxfield, Fedoroff, & Ogrodniczuk, 2003), or else have developed novel treatment combinations for more complex symptom presentations (e.g., Cloitre, Koenen, Cohen, & Han, 2002). As a group, these studies have provided more comprehensive reporting of sample enrollment, demographic, and exposure characteristics, enabling greater confidence in the interpretation and generalizability of findings (see Table 3).

Several of these studies tested interventions on mixed trauma samples, including samples with high prevalence of childhood exposure (Kubany et al., 2004; Resick et al., 2002; Taylor et al., 2003). For instance, Resick et al. (2002) examined treatment efficacy with rape index PTSD in which the vast majority of the study sample (85.8%) had experienced at least one additional major crime victimization, and nearly half (41%) had experienced child sexual abuse. Cloitre and colleagues (2002) developed and evaluated the first manualized individual treatment protocol specifically designed to treat adults with child-onset index trauma. The latter study is particularly notable because it evaluated the efficacy of a treatment designed to address PTSD plus affect regulation problems and interpersonal skills deficits, two common "associated features" of PTSD as delineated in the *DSM-IV* (APA, 1994).

Although less restrictive in terms of trauma exposure, these studies were found to utilize exclusionary criteria that were largely identical to those employed in the ISTSS Practice Guidelines studies, and thus provide little additional opportunity to assess the applicability of efficacy findings to individuals suffering from various severe but common comorbid disorders in addition to PTSD. Of 20 exclusions specified across these studies, 16 related to concurrent psychiatric issues. Exclusion criteria utilized included psychosis (4/4 studies), alcohol/substance problems (3/4), acute suicidality and/or parasuicidal behaviors (2/4), dissociative disorders (1/4), eating disorders (1/4), borderline personality disorder (1/4), and bipolar disorder (2/4).

In contrast, review of newer studies suggests a clear tend toward improved reporting of relevant sample demographic, trauma history, and enrollment data. For instance, all four studies provided detailed information about non-index trauma exposure, and three provided information about comorbid disorders. At least partial information regarding participant exclusion and attrition was provided by all four studies. All four reported numbers of participants assessed, randomized into treatment, and completing treatment. Two of the four (Resick et al., 2002; Cloitre et al., 2002) provided detailed information about attrition and exclusion during the pretreatment phase. In both of these studies, comorbid psychiatric issues contributed significantly to participant exclusion, and in one study (Cloitre et al., 2002) eliminated over one third (37%) of assessed participants. Across these studies, of 659 participants receiving initial assessments, 62% ($n = 406$) were ultimately randomized to treatment, and less than half (45%; $n = 295$) completed treatment.

Overall, these newer studies exemplify the incremental nature of advances in PTSD treatment efficacy research. These studies build upon the accomplishments of the gold standard studies represented in the ISTSS Practice Guidelines while simultaneously addressing many of the omissions and limitations of this earlier research. Nevertheless, questions remain about the applicability of these treatments to individuals presenting in clinical practice with PTSD in addition to severe comorbid disorders or manifestations of acute behavioral disturbance.

Table 4. Pretreatment Exclusion in an NIMH-Funded PTSD Treatment Outcome Study (MH5836 "Treatment Outcome of Fluoxetine vs. EMDR in PTSD")

	Study phase			
	Telephone screen		Baseline assessment	
Reasons for exclusion	*n*	%	*n*	%
Psychiatric/comorbidity				
Severe comorbid psychopathology/organic mental disorder (e.g., bipolar, psychotic disorder; OCD)	112	20.7	11	17.2
Active alcohol/substance use related problem	47	8.7	11	17.2
Current suicidality	8	1.5	1	1.6
Severe dissociation	2	0.4	16	25.0
GAF < 40	6	1.1	5	7.8
Inability to discontinue psychiatric medications	85	15.7	0	0.0
Subtotal	260	48.1	44	68.8
Medical				
Medically unstable	36	6.7	5	7.8
Neurological deficit/traumatic brain injury (TBI)	44	8.1	0	0.0
Nursing/pregnant	9	1.7	0	0.0
Subtotal	89	16.5	5	7.8
Treatment outcome confounds				
Pending trauma-related litigation	20	3.7	0	0.0
PTSD disability	90	16.7	0	0.0
Trauma ongoing	8	1.5	0	0.0
Subtotal	118	21.9	0	0.0
Other (e.g., unstable living situation)	73	13.5	15	23.4
Total excluded	540	100	64	100

Enrollment and Baseline Psychopathology in a Recently Completed PTSD Efficacy Trial

In an effort to further address some of the questions raised in this article, we collected comprehensive sample enrollment data on all potential participants across three critical stages of enrollment (i.e., screening, pretreatment assessment, treatment randomization) in a recently completed treatment outcome study of adult civilian PTSD (NIMH Grant MH5836 "Treatment Outcome of Fluoxetine vs. EMDR in PTSD"). This study is representative of published AHCPR Level A PTSD treatment research for several reasons: (a) adherence to gold standard guidelines for efficacy trials; (b) inclusion of a large mixed trauma sample, including victims of both child- and adult-onset trauma as well as both interpersonal and noninterpersonal forms of exposure; (c) inclusion of both psychotherapeutic and psychopharmalogical interventions; (d) use of broad, community-based recruitment strategies; and (e) utilization of inclusion and exclusion criteria similar to those employed in published research. Of particular interest were the volume and reasons for exclusion during screening, a phase of study enrollment for which few published trials provide data.

Inclusion criteria in this study were presence of PTSD based on diagnostic interview, exposure to a Criterion A traumatic stressor at least one year previously, age 18–5, and lack of prior exposure to study treatments.[1] Exclusion criteria included presence of psychotic/bipolar I disorder, severe dissociation, acute suicidality, acute substance use/abuse; medical issues; and ongoing trauma or PTSD-related disability/litigation (see Table 4). Potential participants underwent an initial telephone screen and likely candidates were invited to complete more extensive in-person pretreatment assessment. Following this assessment phase, eligible candidates were randomized into treatment.

Review of this study's potential subject pool disposition indicates substantial exclusion and attrition from initial screening to study completion. Of the 1,148 potential participants who met study inclusion criteria based on initial screening, approximately one quarter ($n = 299$) were advanced to the pretreatment assessment phase, with the remainder either excluded or self-selecting out prior to enrollment. However, nearly half of all positive telephone screens did not advance to pretreatment assessment

[1] In the present study, 237 individuals were ineligible due to prior exposure to study treatments. Of these, the majority (86%) had prior exposure to fluoxetine. This requirement of novel treatment is a common constraint of psychopharmacological efficacy trials that may bear on external validity of study findings.

due to presence of exclusionary criteria ($n = 540$). The predominant reason for exclusion among this group was the presence of severe comorbid psychopathology (see Table 4).

Finally, approximately one quarter ($n = 309$) of positive telephone screens declined study participation. Of these, more than half ($n = 192$) refused to accept study medications. In contrast, only 1 of 1,148 potential participants refused study psychotherapy. This pattern is suggestive of a self-selection bias that may limit interpretation of study findings to those individuals in clinical practice willing to accept novel medications, and exemplifies the importance of including such information in PTSD outcome research. This potential constraint on external validity has been similarly noted in research on other Axis I disorders (Hofmann et al., 1998).

A similar pattern was noted for disposition during pretreatment assessment. Of the 299 positive phone screens, approximately one quarter ($n = 70$) failed to show for pretreatment evaluation. As a result, 229 individuals signed consent to enroll in the study (representing 20% of the initial potential subject pool). Forty-seven of those enrolled failed to meet full current criteria for PTSD at baseline. Of the remaining 182 study participants, 30 dropped out, and 64 were excluded. Over two thirds of exclusions ($n = 44$) were due to presence of severe psychopathology or significant comorbidity (see Table 4). Ultimately, 48% ($n = 88$) of participants meeting full study inclusion criteria at baseline were randomized to treatment. This percentage falls between those observed for ISTSS Practice Guidelines studies that report versus omit screening data (41% vs. 63%), supporting the contention that published reports on the latter studies may overestimate the percentage of subjects randomized to treatment.

Demographic data on study participants randomized to treatment were as follows. Mean age was 36.1 ($SD = 13.4$). Gender was 83% female. Minority race–ethnicity was 33%. Most participants were currently employed (total 78%: 35% fulltime; 28% part-time). All had at least high school education and 51% graduated college. Household income was $11,000 or below for 30% of participants and $31,000 or above for 31%. Regarding trauma history, 75% had an index trauma involving interpersonal victimization; with trauma onset occurring in childhood (prior to age 18) in 50% of participants. Mean years since occurrence of index trauma was 12.9 ($SD = 11.9$). In terms of baseline psychopathology, mean number of current comorbid Axis I/II diagnoses was 3.2 ($SD = 2.7$).

To better understand baseline differences in traumatized individuals excluded from treatment randomization, measures of psychopathology were assessed for the following four groups of study participants: (a) participants who failed to meet treatment *inclusion* criteria, (b) participants meeting pretreatment *exclusion* criteria, (c) pretreatment dropouts, and (d) treatment randomized participants. Group differences were examined on the Clinician Administered PTSD Scale (CAPS; Blake et al., 1995) the Structured Interview for Disorders of Extreme Stress (SIDES; Pelcovitz, et al., 1997), and a clinician-rated Global Assessment of Functioning (GAF; American Psychiatric Association, 1994).

Analysis of variance indicated significant group differences on GAF, $F(3, 204) = 20.65$, $p < .001$, $\eta_p^2 = .23$; SIDES total score $F(3, 169) = 5.33$; $p < .005$, $\eta_p^2 = .09$; and CAPS total score $F(3, 215) = 38.73$; $p < .001$, $\eta_p^2 = .35$ (see Table 5). Not surprisingly, planned contrasts confirmed that individuals excluded from the study because they failed to meet full criteria for PTSD had lower overall levels of other assessed symptoms. In addition, these analyses supported the hypothesis that individuals excluded from treatment for other reasons were just as symptomatic as randomized participants on overall severity of PTSD, $t(215) = 1.74$, ns. As the exclusion criteria employed in this study were consistent with those used in the majority of efficacy trials included in the ISTSS treatment guidelines cohort, this finding highlights the importance for future research to adopt broader inclusion criteria to determine the extent to which identified interventions work for previously excluded subgroups of individuals with PTSD.

Table 5. Mean Differences in Baseline Symptom and Functioning Indices by Pretreatment Disposition in an NIMH-Funded PTSD Treatment Outcome Study (MH5836 "Treatment Outcome of Fluoxetine vs. EMDR in PTSD")

	CAPS			GAF			SIDES		
Group	*n*	*M*	*SD*	*n*	*M*	*SD*	*n*	*M*	*SD*
PTSD criteria not met	44	46.00[1]	20.45	34	58.74[1]	9.22	19	28.68[1]	15.42
Pretreatment attrition	30	68.20[2]	15.16	30	55.20[1]	6.16	26	30.88[1]	14.75
Randomized	88	74.07[2,3]	13.42	88	56.61[1]	6.25	88	34.30[1,2]	15.33
Pretreatment exclusion	57	78.91[3]	17.59	56	48.02[2]	8.31	40	42.93[2]	15.60
Total	219	68.89	20.18	208	54.44	8.36	173	35.16	15.89

Note. CAPS: Clinician Administered PTSD Scale; GAF: Clinician rated Global Assessment of Functioning; SIDES: Structured Interview for Disorders of Extreme Stress. Numbers in superscript indicate homogeneous subsets.

Finally, baseline analyses revealed that individuals who declined to participate in treatment were actually less symptomatic of PTSD and its associated features (disorders of extreme stress not otherwise specified [DESNOS]), and exhibited higher global functioning, than excluded individuals. Moreover, these individuals exhibited similar profiles to those of randomized participants. This finding challenges the common assumption that individuals who decline participation in PTSD efficacy studies constitute a more impaired subpopulation of trauma survivors than those represented in research cohorts.

Conclusions and Recommendations

Dedicated researchers and scholars have made major strides in the design, evaluation, and dissemination of effective treatments for PTSD, and the improvement in the lives of many trauma survivors because of this research is unquestioned. It is only, however, with continued self-evaluation and correction of past omissions that our field will continue to advance in meeting the needs of individuals whose lives have been impacted by psychological trauma.

Careful examination of the gold standard PTSD efficacy trials informing the 2000 ISTSS Practice Guidelines reveals that as a group these studies underreport vital data—including sample demographics, comorbidity, and enrollment, exclusion and attrition rates—that bear upon external validity of study findings. Posttraumatic stress disorder efficacy studies conducted since compilation of these guidelines exhibit improved reporting of these variables, pairing of established interventions with new and more diverse trauma exposure groups, and adaptation of treatment protocols for previously unstudied forms of trauma exposure. The successful application of these newer studies substantiates the contention that efficacy findings from the body of research comprising the ISTSS Practice Guidelines are likely to be more generalizable to typical trauma patients encountered in clinical practice settings than can be established on the basis of data provided in published reports of the guideline studies. Nevertheless, this newer research used similar exclusion criteria to earlier studies. Accordingly, the efficacy of these interventions remains largely untested for individuals exhibiting more severe forms of comorbid psychopathology either that have been found to co-occur frequently with PTSD, or for which the presence of PTSD engenders elevated risk.

This review indicates the following characteristics of treatment outcome studies can compromise external validity and interpretation of findings: (a) study design, e.g., inclusion and exclusion criteria; (b) subject sampling, e.g., representation of racial–ethnic minorities; childhood-onset trauma victims; (c) self-selection, e.g., pretreatment attrition or treatment dropout; and (d) insufficient reporting of sample characteristic and enrollment data. To ensure the applicability of treatments to the greatest number of survivors of trauma, the following recommendations are offered for future PTSD treatment research.

First, studies should improve reporting of participant enrollment data. It is recommended that inclusion of the following information in published reports be established as a gold standard requirement for future PTSD treatment efficacy research: (a) complete study enrollment data, including precise information on inclusion, exclusion, and attrition beginning with the pre-enrollment screening phase; (b) comprehensive participant demographics and comorbidity profiles; and (c) statistical comparison of potential factors contributing to treatment exclusion, attrition–dropout, and completion.

Second, PTSD efficacy studies should include diverse samples. The subpopulation of trauma survivors excluded from traditional PTSD outcome efficacy research due to severe comorbid psychopathology should be thoroughly characterized to identify both their common and specific treatment needs. Thorough assessment should include trauma exposure history; diagnostic classification; and dimensional assessment of psychopathology and functioning deficits, including self- and affect-regulatory capacities and social adjustment.

Furthermore, treatments currently designated as efficacious for the treatment of PTSD should be evaluated for their capacity to ameliorate symptoms among more impaired trauma survivors. Newer efficacy studies, as highlighted above (i.e., Resick et al., 2002) have applied existing treatments to more diverse trauma populations. Further efficacy research employing broader exclusion criteria, as well as effectiveness studies of naturalistic clinical samples, are needed to determine which and to what extent identified interventions for PTSD work for individuals with more severe comorbid psychopathology. These studies should reassess comorbid conditions measured at baseline, as recent research suggests that PTSD can function as a primary disorder driving other manifestations of psychopathology (McFarlane et al., 2001) and that successful treatment of PTSD may lead to resolution of comorbid disorders (Chard, 2003; Resick et al., 2002).

Third, investigators should develop and evaluate innovative treatments designed to address more complex symptom presentations. Innovative or combination interventions that intentionally target subpopulations of traumatized individuals who have thus far been

underrepresented in PTSD efficacy research due to comorbid disorders or severe behavioral disturbance should receive higher prioritization by funding sources for development and evaluation. Along with PTSD symptoms, such treatments should address common comorbid conditions including dysregulation of affect, problems with attention and concentration, impulsivity, addictive behaviors and disorders, suicidality and self-harming behaviors, somatization, and dissociation. Important recent efforts have been made to assess combination interventions for PTSD and comorbid substance dependence disorders (e.g., Brady et al., 2001; Najavits et al., 1998), as well as for PTSD among more diverse trauma exposure samples (e.g., Cloitre et al., 2002). This latter study provides an example of the promising application of phase-oriented treatment. In this study, the efficacy of an established treatment for emotional processing of trauma memories (modified prolonged exposure) was enhanced by incorporation of prior skills training in affect and interpersonal regulation (STAIR) with a sample of adult survivors of childhood trauma. Further work in this vein is needed.

Fourth, journals should publish negative findings. It is recommended that peer-review journals, the predominant vehicle for dissemination of information about empirically validated clinical practice, set as a priority the publication of studies resulting in negative findings. This is particularly relevant for studies evaluating the efficacy of empirically untested psychotherapeutic interventions, or medications yet unapproved for PTSD, that nevertheless are frequently administered in clinical practice to traumatized individuals. Although efficacy trials with negative findings have historically been less likely to be accepted for publication in peer-review journals, identification and discontinuation of inefficacious and potentially contraindicated treatments for PTSD are at least as important to the advancement of the field as validation and dissemination of those interventions that work.

Fifth, the ISTSS Practice Guidelines should be updated regularly. The ISTSS Practice Guidelines serve as an important tool of dissemination, as well as an acknowledged authority source and therefore regulatory venue for evaluation of efficacious treatments for PTSD. It is therefore recommended that regular update and expansion of these guidelines be set as a priority, so that new and innovative research is incorporated as it becomes available.

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