

Methodological considerations for treatment trials for persons with borderline personality disorder

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BACKGROUND: The National Institute of Mental Health convened an international group of experts to examine the conduct of treatment trials for persons with borderline personality disorder (BPD). The rapid growth of treatment research had led to the recognition that investigators face unique methodological issues with these challenging patients.

METHODS: Conference members reviewed critical aspects of psychotherapy and pharmacotherapy trial design for patients with BPD.

RESULTS: This article summarizes discussions held on March 17-18, 2005.

CONCLUSION: This paper addresses the most pressing issues in sample selection and trial design pertaining to BPD; issues that have bedeviled both investigators submitting applications and reviewers trying to assess the merit of these grants. By disseminating this work, conference members hope to make this process more consistent and productive for all concerned.

KEYWORDS: Borderline personality disorder, treatment, guidelines

INTRODUCTION

Borderline personality disorder (BPD) was introduced into our official nomenclature almost 30 years ago. Until recently, some theoreticians and clinicians viewed BPD skeptically, believing it was either a subthreshold variant of another disorder (eg, major depression, bipolar disorder) or a “wastebasket” term without specific clinical meaning.¹ This skepticism has diminished as a new generation of clinicians and researchers entered psychiatry and clinical psychology. At the same time, research showed BPD to be highly prevalent, to be associated with substantial morbidity and functional impairment,

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and to lead to suicide in up to 10% of patients.² Despite these personal and societal costs, treatment research has lagged behind that of other disorders, such as bipolar disorder and schizophrenia. Investigators have yet to achieve consensus on critical aspects of psychotherapy and pharmacotherapy trial design for patients with BPD, including sample definition, diagnostic and efficacy measures, and other methodologic concerns specific to the disorder.

Nonetheless, with the support and encouragement of advocacy groups and funding agencies, BPD treatment research has grown substantially. Before 1995, only 4 well-designed, double-blind pharmacotherapy studies had been conducted.³⁻⁶ Since then, the results of 14 double-blind, placebo- or comparator-controlled trials have been published.⁷⁻²⁰ Similarly, prior to 1995, there had been only one randomized trial of a manual-based psychotherapy.²¹ Since then, the results of 14 trials have been published.²²⁻³⁵

Although these studies have made significant contributions to the field, they highlight the methodological difficulties inherent in conducting BPD trials. Because investigators have chosen a wide range of symptoms to target, one treatment may seem to be effective for a particular symptom or cluster of symptoms but not others. Studies have been inconsistent with patient selection criteria, as well as in the use of a range of diagnostic and outcome measures. Trial lengths have been relatively brief, which is problematic, given the longstanding nature of BPD. Furthermore, well-validated measures of overall improvement in BPD have not been widely available. Recognizing the need to address these issues, the National Institute of Mental Health (NIMH) convened a conference on March 17-18, 2005, following a series of teleconferences. An international group of 12 experts in the epidemiology, phenomenology, neurobiology, and treatment of BPD was asked to summarize issues that arise in conducting research with these challenging patients. (All are authors of this manuscript.) Panel members chose to consider 2 theoretically separate but overlapping areas, which are the subject of this paper:

- Defining the sample
- Designing a clinical trial.

The panel also developed a series of recommendations and suggestions for future research.

Defining the sample

Defining the study sample is perhaps the researcher's most important task because without a carefully defined sample, conclusions can be misleading. Because of the symptomatic and clinical heterogeneity of BPD, patient

selection is facilitated by the use of structured diagnostic assessments and standardized ratings.

Diagnostic interviews. Four well-regarded structured personality disorder interviews are available: the Structured Interview for DSM-IV Personality (SIDP-IV)³⁶, the Personality Disorder Examination (PDE)³⁷, the Diagnostic Interview for DSM-IV Personality Disorders (DIPD-IV)³⁸, and the Structured Clinical Interview for DSM-IV Personality Disorders (SCID-II).³⁹ All 4 generally produce adequate reliabilities for the BPD diagnosis, and no one instrument is superior. Thus, choice of instrument will be guided by other considerations (eg, experience with a particular instrument, proximity to trainers). In addition, the Revised Diagnostic Interview for Borderlines (DIB-R)⁴⁰ assesses a more complicated BPD construct, including 22 symptoms that are divided into 4 domains and provide 5 continuous scores of borderline psychopathology: 4 section scores and a total DIB-R score. It has shown good discriminant validity as well as good inter-rater, test-retest, and longitudinal reliability.⁴¹ Typically, samples assessed using the DIB-R are more homogeneous than those that use DSM-IV criteria alone.

Defining severity. Severity is a central issue in defining a patient sample for a clinical trial. *Severity* of borderline psychopathology has 2 primary meanings to researchers. First, severity can indicate the patient's overall level of impairment. Functional impairment is reflected not only in symptoms but also in associated disorders (both psychiatric and medical), psychosocial dysfunction, and the quantity and level of psychiatric treatment received over time. Clinical experience suggests that there is a continuum of borderline psychopathology and, for heuristic purposes, 3 levels of severity can be roughly determined.⁴² Patients with *mild* severity manifest the same features of affective instability and reactivity, mood-dependent behavior, and interpersonal difficulties as more severely ill patients with BPD. What often distinguishes these patients is less impulsivity, less disruptive forms of coping—particularly in the areas of self-mutilation and suicidal behavior—and a greater ability to use the treatment relationship to enhance their functioning.

Patients with *moderate* BPD severity are intermittently self-destructive, particularly when they fear abandonment by someone on whom they depend.⁴³ They may function well for extended periods in the context of stable interpersonal relationships and life circumstances. These patients are also able to use a therapeutic relationship effectively, although they are typically more fragile and rely on the therapeutic relationship to fulfill more of their emotional needs than patients

with milder BPD. These patients appear to have a more limited adjustment after a difficult life struggle and see their treatment as a critical element in maintaining stability.

Patients with *severe* BPD lead chaotic lives, with areas of strength overshadowed by a pervasive and chronic pattern of self-defeating behaviors. These patients often heavily utilize psychiatric and medical care, yet treatment results are frequently poor. Over the course of their lives, these patients may relinquish both their determination and ability to function in normative social roles, defaulting to the role of "chronic patient." Many abandon the structure of work or school and are supported by public assistance. They may be unable to maintain interpersonal ties and may become socially isolated. Years of serious dysfunction may be only occasionally interrupted by short periods (ie, weeks or months) of better functioning.

There is no widely accepted method to assess differences in severity. Global Assessment of Functioning (GAF)⁴⁴ and the Clinical Global Impression (CGI)⁴⁵ scale scores have been used—mainly in pharmacotherapy studies—but can be misleading because they combine so many elements into an overall score. Algorithms that include subscales for borderline psychopathology, comorbid disorders, psychosocial functioning, and health care utilization could be helpful in defining severity.

Second, *severity* may refer to acute symptoms present for a set period of time (eg, 1 week, 30 days, 1 year) prior to study entry. Several measures can be used to establish baseline severity so that change can be assessed over time. Such a measure can also be used to determine the severity threshold for a particular study (mild, moderate, or severe borderline symptoms).

Four instruments are candidates for this purpose (TABLE). They vary by mode of administration (interview vs self-report) and in the domains of borderline psychopathology they emphasize. None of the instruments has a large body of psychometric data on which to base recommendations, yet all have preliminary evidence of reliability and validity. Consequently, other important criteria to consider include: (1) the extent to which the measure is likely to provide a clinically meaningful index of acute severity at intake and to be sensitive to change during treatment; (2) its current level of use, ie, "ecological validity" reflected in its citation history; and (3) the rationale for and history of its development (eg, the Zanarini Rating Scale for Borderline Personality Disorder [ZAN-BPD]⁴⁶ reflects a 20-year history with the DIB-R^{40,41} and with the development of the DIPD to capture the DSM criteria^{38,47}). With these considerations

in mind, the 4 scales each provide unique and nonoverlapping information about a patient that, when 1 or more are combined, yields a more complete picture of the patient's disorder. For example, the ZAN-BPD provides an assessment of affective disturbance, cognitive disturbance, impulsivity, and disturbed relationships, whereas the Borderline Evaluation of Severity Over Time (BEST)⁴⁸ has subscales to assess the thoughts and feelings, negative behaviors, and positive behaviors associated with the disorder. While the ZAN-BPD and Borderline Personality Disorder Severity Index (BPDSI)⁴⁹ are clinician-rated, the other scales have the advantage—and disadvantage—of self-report.

Ultimately, the researcher must decide how ill the patient should be, and which symptom domains to emphasize for a particular study. One patient might have serious psychosocial impairment, have received substantial psychiatric care without obvious benefit, and have severe psychiatric symptoms as well. Another might have serious borderline psychopathology (eg, identity disturbance, frequent self-harm), a probable history of psychiatric treatment, and a moderate degree of psychosocial impairment. Studies of symptomatic research volunteers with BPD have tended to focus on acutely symptomatic patients, whereas studies of current patients have often focused on the chronically symptomatic or treatment-resistant patient. This typology differs somewhat, at least in emphasis, from the continuum described above. We believe that both acutely symptomatic patients and chronically disturbed patients are appropriate for clinical trials. In fact, many recent pharmacotherapy trials have focused on acutely symptomatic patients, whereas psychotherapy trials have included more chronically disturbed patients.

Comorbid disorders. Individuals with BPD have high rates of *lifetime* co-occurring disorders, particularly mood and anxiety disorders, substance use disorders, and eating disorders.⁵⁰⁻⁵² Yet research has also found substantially lower rates of *current* co-occurring disorders, suggesting that even the most disturbed patients with BPD have periods relatively free of comorbid Axis I disorders.⁵⁰ This finding is consistent with clinical experience, where comorbid disorders tend to remit and recur.

Naturalistic studies have tended to exclude patients with psychotic or bipolar I disorders because they can complicate diagnosis, or because their severity equals or exceeds that of BPD. These studies have also excluded patients with serious substance misuse (eg, opioid dependence); here it is difficult to reliably diagnose BPD when the patient is actively abusing drugs or alcohol. However,

mild substance abuse (eg, cannabis use) is generally not considered a reason for exclusion by researchers, perhaps because of its frequency in this population. Many treatment studies have also used these rough guidelines.

Beyond these 3 areas of psychiatric comorbidity, investigators have used several approaches. The first approach is to exclude persons with current (ie, past month) or recent (ie, past 3 months) comorbid Axis I disorders. This makes clear that the trial involves the treatment of BPD, not another disorder. Yet this selective approach complicates recruitment, because even during "good" periods, many patients with BPD have a comorbid current (or recent) Axis I disorder. This approach also means that the results of the trial may be hard to generalize when the patients are atypical, or are perceived as atypical.

A second approach is to exclude patients with only the most serious forms of Axis I comorbidity (eg, major depression, posttraumatic stress disorder, bulimia) but to allow current comorbidity that may be viewed as milder (eg, dysthymic disorder, generalized anxiety disorder, eating disorder not otherwise specified). This approach requires careful justification, because this division into more and less serious disorders lacks wide acceptance, and may be arbitrary.

A third approach is to exclude only patients with a current or recent disorder that would make the results of a particular trial difficult to interpret. For example, patients with current major depression might be excluded from a trial of an antidepressant or a mood stabilizer for BPD. An exception would be trials whose purpose is to determine the efficacy of a treatment for patients with BPD who have a specific form of co-occurring Axis I disorder (eg, BPD plus major depressive disorder). Both pharmacologic and psychotherapy trials for BPD patients with complex presentations have been conducted.^{8,31}

These 3 approaches are germane to co-occurring Axis II disorders as well, although there is less evidence on which to draw because, surprisingly, many treatment trials have not assessed these disorders. Some trials were conducted before the development of structured interviews for Axis II, such as SIDP-IV or SCID-II. More recent trials may not have assessed non-BPD Axis II disorders because of such practical concerns as patient burden and cost. In addition, the failure to carefully assess all Axis II disorders may have reflected a belief that some of these disorders constitute dimensions of personality or temperament rather than independent psychiatric disorders (eg, dependent personality disorder). The exclusion of odd cluster personality disorders

are better justified for BPD medication trials for which these disorders may preferentially respond, for example, trials of atypical antipsychotics.⁵³

In some ways, this issue is easier to address in medication trials, which tend to be shorter than psychotherapy trials. It may also be more essential to determining their outcome, because most medications tested in patients with BPD have already shown efficacy in treating another disorder in more general samples (eg, depressed patients). For both medication and psychotherapy trials, it is important to assess lifetime and current comorbid Axis I disorders and the full array of Axis II disorders. Even when comorbid disorders are not a reason for exclusion, researchers should document their presence, and perhaps control for them in analyses or examine them as moderators of treatment response.

Concurrent psychotropic medications. Research shows that the majority of patients with BPD are prescribed psychotropic medications for sustained periods.^{54,55} Many patients take multiple concurrent medications despite the lack of evidence supporting this practice. This prescribing pattern persists despite the heightened rate of obesity and related chronic illnesses associated with this clinical practice.⁵⁶ Interestingly, the only relevant study of the effect of polypharmacy found that BPD patients fared about as well with 1 medication as with 2.²⁰ Medication trials typically proscribe the use of other psychotropic medications, or only allow low and/or stable doses of sedative-hypnotics, or tranquilizing medication taken for agitation on as-needed basis (ie, PRN). Clearly, it is not possible to assess the efficacy of a psychotropic medication in a double-blind, placebo, or comparator-controlled trial when patients are taking other medication at therapeutic doses. On the other hand, although the use of concomitant medication for sleep or agitation can be problematic, allowing such use can facilitate recruitment, either because a patient would refuse to join a study if denied such medication, or his or her treating psychiatrist would recommend against joining the trial. Still, even limited use of another psychotropic agent can complicate the interpretation of study results and requires justification.

Whether to allow standing psychotropic medications during psychosocial treatment trials is more complicated. One question is how severely ill the patient should be to enter a given trial. In other words, is the study aim to determine the efficacy of a therapy for all patients with BPD, or a particular subset? Here, the issue of severity in its several forms comes into play. When a study aims to treat severely ill patients with BPD, is the focus on overall severity? Current severity? If the focus is on the former overall severity, one may actually be

assessing chronicity and treatment resistance as well as level of borderline psychopathology. In the latter current severity situation, patients may experience severe BPD symptoms and yet function without treatment (or perhaps they cannot afford treatment). In the former, almost all potential patients are prescribed medication; in the latter, few patients take medication. Thus, it is crucial to determine whether the purpose of the trial is to improve the functioning of patients who have already received significant psychiatric care, or to improve the functioning of patients who experience BPD symptoms but are relatively treatment naïve and able to function independently.

There are several options for handling the use of psychotropic medications by patients enrolled in clinical trials: (1) enrolling only patients not currently receiving psychotropic medication; (2) discontinuing all psychotropic medications prior to study entry; (3) continuing a patient's medication regimen at the time of study entry; (4) similar to option 3, continuing a patient's medication regimen at the time of study entry, but with a stabilization component prior to entry; (5) choosing a standard, invariable medication regimen for all patients; (6) allowing a study psychiatrist (or the patient's community psychiatrist) to flexibly determine medication for individual patients; or (7) allowing medication according to a predetermined algorithm. If concomitant medication is allowed, the investigator will need to carefully document the drug, the drug class, and the dosage, and update this information periodically. This information can then be used to compare medication usage in the treatment groups.

No option is perfect, and investigators may need to match the option selected to the particular study aims. Recruitment will be more difficult when an investigator rigorously proscribes concomitant medication, increasing the cost and duration of a study. Also, the results of trials that do not allow concomitant medications may be seen as having less generalizability, and hence less ecologic validity. Yet, allowing concomitant medications may complicate the interpretation of study results: are the findings due to the psychotherapy being studied, the medication, or some interaction of the 2? Because there are no "right" answers to this dilemma, investigators need to clearly justify the reasons behind their choice and acknowledge its limitations.

Psychosocial treatment use in psychotherapy or medication studies. Research protocols should specify whether a patient is receiving another psychosocial treatment outside the proposed intervention. Most protocols prohibit a patient's involvement in another type of psychosocial intervention for obvious reasons: disentangling the effects of

more than one treatment may be difficult or impossible. On the other hand, some newer BPD treatments (eg, Systems Training for Emotional Predictability and Problem Solving [STEPPS])²³ are "adjunctive," and added to whatever therapy the patient is currently receiving; thus, there is no expectation that the patient's current treatment regimen will be curtailed. Participation in leaderless self-help groups such as Alcoholics Anonymous or Gamblers Anonymous may be permitted; the motivation to allow attendance of these groups may vary from study to study. In some trials, it may be thought that disallowing attendance may adversely affect recruitment; in others, an Institutional Review Board may judge it unethical to prohibit attendance.

Medication trials should prohibit new psychosocial treatments during their course, because this can introduce a confound whose effects are difficult to control. Established therapies (eg, those having already lasted ≥ 3 months) may be viewed as acceptable, and when allowed, should be documented.

Designing the trial

Measuring outcome. BPD outcome research is gradually maturing. Until recently, the field lacked reliable measures to assess the severity of the DSM-IV BPD criteria or the overall severity of borderline symptoms. The absence of reliable comprehensive measures led to the use of multiple ratings, often culminating in the reporting of 20 to 30 outcomes in a single trial, with the inevitable result of complicating interpretation of study results. Further, different studies used different measures to assess the same symptoms, a practice that has hampered meaningful comparison of findings across studies.

The introduction of the ZAN-BPD,⁴⁶ the Borderline Symptom List (BSL),⁵⁷ the BPDSI,⁴⁸ and the BEST⁴⁷ (TABLE) has improved this situation, yet additional research on these measures is needed. Also, there is no consensus on the most clinically meaningful outcomes pertaining to overall severity of borderline symptoms. The "gold standard" outcome might be a particular score that signifies low severity (eg, a score of 1 or 2 on the CGI Improvement scale⁴⁵ indicating "very much" or "much" improvement). It might also be a percent decline from baseline score (eg, 25% to 50% decrease on the ZAN-BPD), though this percentage is arbitrary. In either case, work is needed to determine whether that score or percentage improvement is clinically meaningful for each measure. Also, it is reasonable to compare the performance of these measures in future psychotherapy and medication trials. For outcome research in

TABLE

Scales to assess severity and change in persons with borderline personality disorder

Instrument	Citations	Mode of administration	Content	Format	Comments
BPD Severity Index	Arntz A, et al. Reliability and validity of the Borderline Personality Disorder Severity Index. <i>J Pers Disord.</i> 2003;17:45-59.	Rater	Semistructured inquiry about the frequency and severity of specific symptoms of BPD in a specified time (3 mo).	Criteria are scored on an 11-point scale reflecting frequency of occurrence, and a total score is derived to represent overall severity of BPD for a given period.	Good inter-rater and test-retest reliability as well as sensitivity to change. Also good discriminant and convergent validity.
Zanarini Rating Scale for BPD (ZAN-BPD)	Zanarini MC, et al. Zanarini Rating Scale for Borderline Personality Disorder (ZAN-BPD): a continuous measure of DSM-IV borderline psychopathology. <i>J Pers Disord.</i> 2003;17:233-242.	Rater	Questions from the DIPD-IV were adapted to reflect a 1/2-wk time period.	Each BPD criterion is rated on a 0 to 4 anchored scale reflecting severity of symptoms.	Good convergent and discriminant validity. Also good inter-rater and test-retest reliability as well as sensitivity to change.
Borderline Evaluation of Severity over Time (BEST)	Pfohl B, et al. Reliability and validity of the Borderline Evaluation of Severity over Time (BEST): a new scale to measure change and severity in borderline personality disorder. In press.	Self-report	15 items: 12 "negative" items modeled on the BPD criteria and 3 "positive" coping behaviors. Items are rated for the past 7 or 30 days (or other time period).	The negative items are scored on a 1 to 5 ordinal scale from "none/slight" to "extreme." The positive behaviors are scored on a 1 to 5 ordinal scale from "almost never" to "almost always."	Adequate test-retest reliability, high internal consistency, and high discriminant validity. Sensitive to clinical change as early as week 4.
Borderline Symptom List (BSL)	Bohus M, et al. Psychometric properties of the Borderline Symptom List (BSL). <i>Psychopathology.</i> 2007;40:126-132.	Self-report	95 items reflecting subjective distress and "intrapsychic strain" are rated for the last week. A briefer version that includes 21 of the original items and 10 behavioral markers of BPD has been developed more recently.	Items reflecting subjective distress are rated on a 0 to 4 ordinal scale, from "not at all" to "very strong." Behavioral markers are rated on a 0 to 4 ordinal scale from "not at all" to "daily or more often."	High internal and test-retest reliability; sensitive to change.

BPD: borderline personality disorder; DIPD-IV, Diagnostic Interview for DSM-IV Personality Disorders.

BPD to be considered comparable to that of better-studied disorders, the field needs to adopt both 1 or 2 standards of efficacy and 1 or 2 instruments to assess that outcome.

Additionally, because BPD is complex, with symptoms in multiple domains, investigators may reasonably focus on symptoms in only 1 or 2 of these areas (eg, mood instability, impulsivity). At this point, the field lacks validated interviews or self-report measures developed specifically to assess detailed changes in specific domains of borderline psychopathology (eg, affective lability, disturbed cognitions, disturbed relationships).

Control conditions. The typical control condition in a pharmacotherapy trial is a placebo and/or an active comparator medication, whereas several different control conditions have been used in BPD psychotherapy trials. These include: (1) wait lists; (2) treatment as usual (TAU); (3) treatment by experts; and (4) another type of manualized treatment.

In selecting a control condition, the most important issue is its potency. Wait lists are losing favor because they provide no treatment. This can be problematic in lengthy trials with volatile patients with BPD. Wait lists have also

lost favor because they provide no control for therapist time, attention, or any of the other nonspecific aspects of psychotherapy.⁵⁸ It is even possible that relegation to a waiting status for treatment might have a toxic, “nocebo” effect.⁵⁹ Thus, it is not surprising that any modestly active treatment is likely to prove superior to a wait list.

Using an “active” comparison, such as a manual-based supportive psychotherapy, can control both for therapist time and attention and for the “common factors” of psychotherapy, such as social support, hope, and therapeutic alliance.⁶⁰ Yet this is a potentially overly rigorous test of a newly developed psychotherapy, inasmuch as the common factors themselves account for much of the outcome variance in psychotherapy trials. In fact, they account for a greater percentage than the specific techniques of most experimental interventions.⁶¹ These trials also require a larger sample to provide the statistical power to detect differences between groups.

Comparing an experimental treatment to an already validated psychotherapy for BPD is another design option. This, too, is likely to require a large sample to discern between-treatment differences, and the lack of a difference may not be conclusive. Further, these trials may be viewed as a “horse race,” and may not be entirely fair, because each treatment may provide unique elements that the study is unable to fully distinguish. One might inappropriately conclude from such a trial that a valuable new treatment is “ineffective” because it may not perform as well as the previously validated treatment.

Thus, the choice of the control conditions will depend on the investigator’s goals. The rigor of the control condition should increase as the experimental treatment becomes better studied and more widely disseminated. For a preliminary (or pilot) study, a wait list might be appropriate. For an initial RCT, TAU may be appropriate, as a comparison with a validated psychotherapy may provide too rigorous of a test. (However, it should be noted that TAU is often very heterogeneous and may involve very little treatment for some patients.) Once a treatment has developed support through several randomized controlled trials, a larger multisite study might use a manual-based comparator, such as supportive psychotherapy. Later, comparisons with community experts or validated psychotherapies are in order.

Future directions

Effectiveness studies. No effectiveness studies have been conducted on any of the psychotherapies with some degree of proven efficacy (dialectical behavior therapy,²¹ men-

talization-based treatment,²² schema-focused therapy,²⁸ transference-focused psychotherapy,²⁵ and STEPPS²³). It would seem wise to move relatively rapidly from efficacy studies that replicate the findings of the therapy’s originator to such studies. This is because the vast majority of patients with BPD are treated in the community and not in academic medical centers.

Focal psychotherapies. Psychosocial interventions that focus on specific symptom domains, rather than targeting the entire syndrome, might be developed. Simply put, many clinicians and treatment centers are unable to provide comprehensive treatments, even when evidence-based. Moreover, many patients seek briefer treatments addressing more immediate concerns. It may be that, in the future, treatment will be modularized and patients will only participate in modules germane to their most pressing symptoms. For example, Gratz and Gunderson⁶² and Weinberg and colleagues⁶³ recently described 2 treatment programs focused on self-mutilation.

Pharmacotherapy. Many classes of psychotropic drugs have shown efficacy in placebo- or comparator-controlled trials of patients with BPD. Nonetheless, it remains unclear which class is the most effective for treating BPD, or at least some of its symptoms (eg, impulsivity). We encourage NIMH and other funding sources to support large-scale treatment studies, which compare the efficacy of different classes of psychotropic medications and studies that assess the efficacy of polypharmacy. We also encourage the development of medications specifically aimed at BPD.

“Real world” treatments. The time is also ripe for studies assessing designs closer to “real world” treatment situations. Specifically, there is a need for research on combined treatment: psychotherapy plus medication vs psychotherapy (or medication) alone. In one of the few such studies, Soler et al¹⁶ reported that dialectical behavior therapy (DBT) and olanzapine combined were superior to DBT alone; a finding suggesting combined treatment may be fruitful.

Caveats pertaining to changes in DSM-V. This article has suggested measures for assessing the BPD diagnosis as defined by the current DSM system. It has also suggested measures for assessing change in borderline psychopathology as defined by the current DSM system. However, there is a substantial chance that dimensionality will be included in the BPD criteria in DSM-V, which is due to be completed in 2013. If these dimensional changes are measures of severity, the current instruments will have to be revised to accommodate these changes. But if more basic changes are included in the DSM-V definition of BPD, new measures to assess

the presence of this new construct and to assess changes in its severity must be developed. It is possible that the DSM-V will define BPD (and other Axis II disorders) by elements of normal personality.⁶⁴ Although various measures of this type of system exist (eg, Revised NEO Personality Inventory [NEO-PI-R]⁶⁵; Schedule for Nonadaptive and Adaptive Personality [SNAP]⁶⁶; Dimensional Assessment of Personality Pathology [DAPP]⁶⁷), they tend to be self-reports. Additionally, none have been developed to assess change over the relatively short periods of time found in most medication (8 to 12 weeks) and psychotherapy trials (several months to 1 year). This is particularly so in medication trials in which assessments of change are typically made each week. Regardless of the particulars, such instruments would need to be developed and their sensitivity to change assessed and found adequate.

CONCLUSIONS

In summary, research concerning the treatment of BPD has progressed in recent years. However, much needs to be learned concerning the psychotherapy and medication treatment of patients with BPD. This article has addressed

the most pressing issues in treatment research pertaining to patients with BPD; issues that have bedeviled both investigators submitting applications and reviewers trying to assess the merit of these applications (and the resulting publications). Only time will tell how the field unfolds. ■

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