On the Threshold of Disorder: A Study of the Impact of the DSM-IV Clinical Significance Criterion on Diagnosing Depressive and Anxiety Disorders in Clinical Practice

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Background: Two recent reanalyses of epidemiologic studies found that adding a clinical significance criterion reduced disorder prevalence. Patients presenting for clinical care are usually distressed or impaired by their symptoms; thus, the DSM-IV clinical significance criterion might have little impact on diagnosis in clinical practice. In the present report from the Rhode Island Methods to Improve Diagnostic Assessment and Services (MIDAS) project, we examine the impact of the DSM-IV clinical significance criterion on diagnostic frequencies of depressive and anxiety disorders in psychiatric outpatients.

Method: 1500 psychiatric outpatients were evaluated with the Structured Clinical Interview for DSM-IV. We determined the percentage of patients who met symptom criteria but did not meet the DSM-IV clinical significance criterion for major depressive disorder, posttraumatic stress disorder (PTSD), generalized anxiety disorder (GAD), social phobia, specific phobia, panic disorder, and obsessive-compulsive disorder.

Results: No patient who met the symptom criteria for current major depressive disorder or PTSD failed to meet the clinical significance criterion. Less than 2% of patients meeting the symptom criteria for current GAD did not meet the clinical significance criterion. There was variability among the remaining anxiety disorders in the percentage of symptomatic patients who met the clinical significance criterion.

Conclusion: In psychiatric patients, the clinical significance criterion had little impact on diagnosing major depressive disorder, GAD, and PTSD, disorders that are defined, in part, by disruptions of daily regulatory domains such as sleep, appetite, energy, and concentration. In contrast, the clinical significance criterion had a greater impact in determining whether phobic fears, obsessive thoughts, and panic attacks were sufficiently distressing or impairing to qualify for disorder status.

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The boundary used to distinguish psychiatric disorder from normality remains a subject of interest. Because of concerns about pathologizing mild, but normal, variants of human behavior and cognition, a clinical significance criterion was added to approximately half of the criteria sets in DSM-IV.[1] The DSM-IV clinical significance criterion generally embodies 2 distinct, albeit related, concepts—subjective distress and role impairment. Spitzer and Wakefield[1] recently critiqued the conceptual justification for this criterion; nonetheless, it is currently a component of most of the mood and anxiety disorder criteria sets.

Narrow and colleagues[2] examined the impact of the clinical significance criterion on the prevalence of psychiatric disorders in the Epidemiological Catchment Area and National Comorbidity Survey (NCS) studies. The premise of their analysis was that the reported disorder prevalence rates in these 2 community epidemiologic studies were too high and that some nondisordered individuals were incorrectly classified as disordered. In their study, the clinical significance criterion was operationalized in terms of treatment seeking (i.e., reporting symptoms to a professional or taking medication for the symptom) or "a lot" of impairment caused by the symptoms. As expected, they found that raising the threshold to define a disorder by requiring the presence of this criterion reduced the overall prevalence rates of psychiatric disorders in the community samples. The authors concluded that these lower rates were more valid than the rates reported in the original publications from these epidemiologic studies. However, as noted by Wakefield and Spitzer[3] in

an accompanying commentary, the DSM-IV clinical significance criterion is not synonymous with seeking treatment. They also indicated that requiring "a lot" of impairment to diagnose a disorder might overlook mildly and moderately severe disorders.

Slade and Andrews[4] examined the impact of the clinical significance criterion on the prevalence of major depressive disorder (MDD), generalized anxiety disorder (GAD), obsessive-compulsive disorder (OCD), social phobia, and posttraumatic stress disorder (PTSD) in the Australian National Survey of Mental Health and Well-Being. They found that the clinical significance criterion decreased the prevalence of most disorders by at least 20%, and the presence of the clinical significance criterion was associated with more impairment, distress, and seeking of psychiatric care on independent measures of these variables.

We are unaware of any study examining the impact of DSM-IV's clinical significance criterion on diagnosis in clinical practice. Because patients presenting for clinical care are usually distressed or impaired by their symptoms, it is possible that this criterion has little actual impact on clinical practice. However, patients often have more than 1 diagnosis-related problem when they seek treatment. DSM-IV distinguishes between principal and additional diagnoses based on the reasons why patients present for treatment. The principal diagnosis refers to the primary reason for seeking treatment, whereas other disorders are considered additional diagnoses. While the clinical significance criterion may have little influence on the diagnosis of principal disorders, this criterion might be important in diagnosing the presence of comorbid conditions that are not the principal reason for seeking treatment. In the present report from the Rhode Island Methods to Improve Diagnostic Assessment and Services (MIDAS) project, we examined the impact of the clinical significance criterion of DSM-IV on diagnostic frequencies of depressive and anxiety disorders for individuals who present for care.

METHOD

Subjects

One thousand five hundred psychiatric outpatients were evaluated with a semistructured diagnostic interview in the Rhode Island Hospital Department of Psychiatry outpatient practice. This private practice group predominantly treats individuals with medical insurance (including Medicare but not Medicaid) on a fee-for-service basis, and it is distinct from the hospital's outpatient residency training clinic that predominantly serves lower income, uninsured, and medical assistance patients. The primary referral sources to the practice are primary care physicians and psychotherapists, though data on referral source were not systematically recorded. Not all patients who presented for treatment participated in the study. As described elsewhere, patients who did and did not participate in the study were similar in gender, education, marital status, and scores on self-administered symptom questionnaires.[5]

The patients were interviewed by a trained diagnostic rater who administered a semistructured diagnostic interview. The Rhode Island Hospital institutional review committee approved the research protocol, and all patients provided informed, written consent. Details regarding interviewer training and supervision are presented in other reports from the MIDAS project.[5–8] Throughout the study, ongoing supervision of the raters consisted of weekly diagnostic case conferences involving all members of the team. In addition, every case was presented for review to the senior author. During the course of the study, joint-interview diagnostic reliability information, in which one rater conducted the interview while another observed and made independent ratings, was collected on 47 patients. Reliability was examined only for those disorders diagnosed in at least 2 patients. For the depressive and anxiety disorders, the kappa coefficients of agreement were as follows: MDD ($\kappa = 0.91$), panic disorder ($\kappa = 1.0$), social phobia ($\kappa = 0.84$), OCD ($\kappa = 1.0$), specific phobia ($\kappa = 0.91$), GAD ($\kappa = 0.93$), and PTSD ($\kappa = 0.91$). Because the clinical significance criterion is a required feature to make a diagnosis, high diagnostic reliability indicates that the clinical significance criterion was rated reliably.

Measure

The core of the diagnostic evaluation was the January 1995 patient version of the Structured Clinical Interview for DSM-IV (SCID).[9] The prevalence of social phobia and PTSD may have been influenced by some modifications we made to the SCID. The SCID screening question for social phobia was supplemented with questions about 12 specific social situations. Regardless of how individuals responded to the SCID's screening probe about anxiety regarding public speaking or eating in front of others, they were also asked if they felt more fearful, anxious, or nervous than most people when saying something in a group of people, business meetings, one-on-one conversations, etc. The SCID screening question for PTSD was supplemented with questions about 12 specific traumatic events if the patient answered no to the screening question. As reported elsewhere, this increased the prevalence of individuals with a trauma history, but had minimal impact on the diagnosis of PTSD.[10]

For MDD and PTSD, we modified the SCID to record on an item-by-item basis whether the symptoms were current or present only in the past. Thus, for MDD and PTSD, we were able to determine the impact of the impairment/distress criterion for current as well as lifetime diagnoses. For GAD, we determined the impact of the clinical sig-

Table 1. Prevalence of Current DSM-IV Depressive and Anxiety Disorders and Symptom Presence Without Meeting the Clinical Significance Criterion in 1500 Psychiatry Outpatients

	Current Disorder		Principal Diagnosis		Additional Diagnosis		Symptom Criteria Only	
Disorder	N	%	N	%	N	%	N	%
Major depressive disorder	690	46.0	537	35.8	153	10.2	0	0.0
Posttraumatic stress disorder	183	12.2	49	3.3	134	8.9	0	0.0
Generalized anxiety disorder	252	16.8	43	2.9	209	13.9	3	0.2

nificance criterion for current disorder only, because the SCID does not assess past GAD. For the remaining disorders (social phobia, specific phobia, panic disorder, and OCD), we could examine the impact of the clinical significance criterion for lifetime diagnoses only.

The structure of the SCID follows the order of the DSM-IV diagnostic criteria. Symptom inclusion criteria are assessed first, followed by an evaluation of the impairment/distress criterion. The SCID uses somewhat different questions for different disorders to assess the impairment/distress criterion. For example, the question for MDD is, "Has (depression/own equivalent) made it hard for you to do your work, take care of things at home, or get along with other people?" In contrast, multiple questions were asked for social phobia: "How much did (social phobic symptoms) interfere with your life? How much has the fact that you have this fear bothered you?" The questions on the SCID regarding impairment and distress are preceded by the direction that they should be asked if the interviewer is unclear whether the symptoms are clinically significant. Thus, the interviewer is supposed to consider information from the entire interview when determining whether the clinical significance criterion is met. This is in contrast to fully structured interviews such as the Diagnostic Interview Schedule, which are used by lay interviewers in community-based epidemiologic studies in which interviewers rate the clinical significance based only on the response to specific questions.

Each SCID item was entered into the database, thereby enabling us to determine the number of individuals who met the symptom inclusion criteria but were not diagnosed with the disorder because they did not meet the impairment/distress criterion. We focused on depressive and anxiety disorders because each includes an impairment/distress criterion as part of the DSM-IV diagnostic criteria, they are among the most frequent disorders in clinical and community-based epidemiologic studies, and they are often diagnosed as additional, comorbid disorders as well as principal disorders. Dysthymic disorder was not included in the analysis because it often was comorbid with MDD and it was sometimes difficult to rate the impairment/distress criterion apart from MDD. Agoraphobia was not included in the analysis because it was almost always diagnosed in the presence of panic disorder.

For current diagnoses of MDD, PTSD, and GAD, we followed the DSM-IV convention to distinguish between principal and additional diagnoses: the principal diagnosis referred to the features of the disorder that the patient indicated was the main reason for seeking treatment; all other diagnoses were considered additional diagnoses. For the 4 anxiety disorders (panic disorder, social phobia, specific phobia, OCD) that were examined only from the lifetime perspective, we did not attempt to distinguish between principal and additional diagnoses because patients often did not seek treatment for the disorders.

For each disorder, we determined the percentage of patients that met the DSM-IV criteria for the disorder (including meeting the clinical significance criterion) and the percentage who met the symptom inclusion criteria but not the clinical significance criterion.

RESULTS

The majority of the 1500 patients were female (61.5%, N = 923), white (91.4%, N = 1371), high school graduates (89.3%, N = 1340), and married (41.2%, N = 618) or single (31.2%, N = 468). The mean age of the patients was 37.8 years (SD = 12.6).

The data in Table 1 show the frequency of current MDD, PTSD, and GAD. When present, MDD was usually the principal diagnosis, whereas PTSD and GAD were more often diagnosed as comorbid disorders. No patient who met the symptom criteria for current MDD and PTSD as an additional, comorbid diagnosis failed to meet the impairment/distress criterion. Less than 2% of patients meeting the symptom criteria for GAD did not also meet the impairment/distress criterion.

Considering lifetime diagnostic rates, all disorders were diagnosed in at least 10% of patients, with MDD the most frequent and OCD the least common (Table 2). In the foregoing discussion, meeting diagnostic criteria refers to satisfying the symptom and clinical significance criteria, whereas meeting symptom criteria only refers to satisfying the symptom criteria but not the clinical significance criterion. Virtually everyone who satisfied the symptom criteria for MDD and PTSD satisfied the diagnostic criteria, whereas there was variability among the remaining anxiety disorders in the percentage of symptomatic patients who met the diagnostic criteria. Slightly less than half of the patients who satisfied the symptom

Table 2. Prevalence of Lifetime DSM-IV Depressive and Anxiety Disorders and Symptom Presence Without Meeting the Clinical Significance Criterion in 1500 Psychiatry Outpatients

	Lifetime Disorder Prevalence[a]		Symptom Criteria Only			
Disorder	N	%	N	%	Either Symptom or Diagnostic Criteria, N[b]	Patients With Symptoms With Disorder, %[c]
Major depressive disorder	979	65.3	0	0.0	979	100.0
Posttraumatic stress disorder	300	20.0	2	0.1	302	99.3
Panic disorder	336	22.4	91	6.1	427	78.7
Social phobia	472	31.5	159	10.6	631	74.8
Specific phobia	184	12.3	206	13.7	390	47.2
Obsessive-compulsive disorder	153	10.2	37	2.5	190	80.5

[a]Lifetime prevalence of generalized anxiety disorder was not ascertained.
[b]The numbers in this column represent the total numbers of patients with the disorder and those with symptom criteria.
[c]The percentages in this column represent the percentages of patients who met the symptom criteria who were diagnosed with a disorder. For example, 99.3% (N = 300) of the 302 patients who met the symptom criteria for posttraumatic stress disorder received the diagnosis.

criteria for specific phobia met the full criteria, whereas more than three quarters of the patients with recurrent panic attacks met the full criteria for panic disorder.

DISCUSSION

There are several reasons mental health professionals should care about the boundary used to distinguish between mental disorder and normality. The boundary influences estimates of the prevalence of psychiatric disorders in the community, which in turn influences the allocation of public health expenditures. Whether or not a problem is considered a disorder influences medical insurance reimbursement. The breadth of definitions of mental disorder has varied in mental health parity statutes in different states.[11] Determination of the presence of mental disorder has potential legal implications in criminal cases and decisions regarding disability determinations. Lack of conceptual clarity regarding the boundary used to define a mental disorder can contribute to abuses of psychiatric diagnoses as a means of controlling or stigmatizing socially undesirable behavior. Finally, lack of clarity in conceptualizing a fundamental, core issue such as the distinction between disorder and normality may reduce confidence in the profession as an authority regarding diagnostic issues and controversies.

It should be noted that boundary issues and controversies are not unique to psychiatry and psychology and are as relevant to nonpsychiatric medical problems. Recent changes in the thresholds defining obesity, hypertension, and hypercholesterolemia have generated significant attention in the news media. In fact, boundary questions may attain even greater visibility during the coming years as technological advances improve the detection of internal organ structural abnormalities. For example, there has been a recent growth of facilities offering full-body imaging procedures to detect occult illnesses in their early stages. The clinical significance of the early detection of abnormalities is unknown because the natural, untreated course of lesions detected at an early stage is unknown. Consequently, the boundary between normal variation and pathology will be challenged as the tools to detect gross abnormalities improve in the absence of understanding pathophysiologic mechanisms producing clinically significant pathology. While it may be somewhat reassuring that uncertainty in distinguishing disorder from normality is not limited to the mental health field, almost all mental disorders, in contrast to most medical disorders, represent quantitative deviations from a normative concept, therefore this issue has significance for the mental health field.

To our knowledge, the present study is the first to examine the impact of the clinical significance criterion in a patient setting. We found that the impact of this criterion on disorder prevalence varied among the anxiety and mood disorders. Practically no patients meeting the symptom criteria for current MDD, GAD, and PTSD failed to meet the clinical significance criterion. One interpretation of this result is that the DSM-IV clinical significance criterion does not function as intended for these disorders when evaluating psychiatric patients. It is of interest that each of these disorders is diagnosed polythetically, with the symptom inclusion criteria represented by a list (or multiple lists in the case of PTSD) of signs and symptoms, a minimum number of which must be present. In contrast, the other anxiety disorders are diagnosed when the necessary, core features are present. Reaching the DSM-IV minimum symptom threshold for the polythetically defined disorders was almost always accompanied by clinically significant distress or impairment. Major depressive disorder, GAD, and PTSD are not only defined polythetically, but are also characterized by vegetative and cognitive symptoms. Defining features of these disorders include disruptions of daily regulatory domains such as sleep, appetite, energy, and concentration, whereas this is not true of the other anxiety disorders. While we did not equate such disruptions with the DSM-IV concept of functional impairment, they invar-

iably were associated with either subjective distress or role impairment. In contrast, it is potentially easier to adapt to phobic fears, obsessive thoughts, and panic attacks in order to minimize distress and impairment.

For MDD, the clinical significance criterion had a greater impact on disorder prevalence in the community epidemiologic studies than in the present study. In the Australian National Survey of Mental Health and Well-Being, the clinical significance criterion reduced the prevalence of current MDD by 19%[4]; in the NCS reanalysis, the prevalence of lifetime MDD decreased by 36%.[2] One possible reason for this discrepancy is that the individuals seeking treatment in the present study were severely depressed and thus uniformly found to meet the clinical significance criterion. However, inconsistent with this is that many of the patients would not have qualified for an antidepressant efficacy trial because their scores on the Hamilton Rating Scale for Depression were too low.[12] Alternatively, the differences between studies may be due to the method of assessing the clinical significance criterion. In the present study, highly trained raters, many of whom were Ph.D. psychologists, used their clinical judgment to directly apply the DSM-IV clinical significance criterion. In the Australian survey and the NCS, a fully structured interview was administered by lay interviewers. In the NCS reanalysis, the clinical significance criterion was met if the symptoms resulted in treatment seeking or "a lot" of interference in functioning,[2] whereas in the Australian survey, "a lot" of functional impairment or being upset with oneself for having the symptoms was required.[4] It seems that the threshold used to define clinical significance in these studies was higher than the one articulated in DSM-IV and used in the present study, thereby accounting for discrepancy. Thus, the impact of the clinical significance criterion on disorder prevalence rates in these epidemiologic studies may have been overestimated, though this might vary by disorder.

There is some concordance between the results of the present study and our earlier findings regarding clinician underdiagnosis and desire for treatment for comorbid conditions. We previously reported that clinicians underrecognize diagnostic comorbidity,[5] a finding that has been independently replicated by 3 other research groups.[13–15] In a separate report, we found that patients' desire for treatment for comorbid Axis I disorders varied by disorder.[16] It is evident when summarizing across these reports that the disorders that were less likely to be overlooked by clinicians were also those for which patients were more interested in having treatment and that were more often associated with clinically significant distress or impairment. Specifically, MDD, PTSD, and GAD seemed to be more virulent than the other disorders assessed, as they were less likely to be underrecognized by clinicians, the clinical significance criterion was nearly always reached when the symptom criteria were present, and patients were more likely to want treatment to address them even when they were comorbid disorders. In contrast, OCD, social phobia, and simple phobia were very often underrecognized by clinicians, the clinical significance criterion was often not met in patients with phobic fears and obsessive-compulsive symptoms, and patients often did not want treatment to address them even when they were diagnosed.

A limitation of the present study was that only mood and anxiety disorders were studied. The other disorder categories either were not sufficiently frequent to be examined, or, in the case of substance use disorders, do not include a separate impairment/distress criterion. Another limitation was that we were able to look at the impact of the clinical significance criterion on current diagnosis for only 3 disorders. It also would have been desirable to have rated impairment and distress separately in order to examine the relationship between the two constructs and the impact of each in establishing disorder presence. It would be possible to operationalize the DSM-IV clinical significance criterion and make ratings on a Likert scale with defined anchor points of the level of distress and impairment; this would be informative in determining the respective influence of each of the constructs on diagnosis. Finally, the sample was drawn from a single large general adult outpatient private practice setting in which the majority of the patients were white, female, and in their thirties and forties. It will be important to replicate and extend the present findings to samples that have different demographic and clinical characteristics.

In conclusion, the clinical significance criterion had practically no impact on the diagnosis of current MDD, PTSD, and GAD. Lifetime rates of other anxiety disorders, which include current as well as past diagnoses, were differentially affected by the clinical significance criterion. However, clinicians are most concerned about diagnosing current disorders rather than establishing lifetime histories of pathology. Future research should examine the impact of the clinical significance criterion across an array of current disorders. If, in fact, the clinical significance criterion has little influence on the diagnosis of all, or almost all, current disorders, then consideration should be given to its elimination from the next edition of the DSM.

Disclosure of off-label usage: The authors have determined that, to the best of their knowledge, no investigational information about pharmaceutical agents has been presented in this article that is outside U.S. Food and Drug Administration–approved labeling.

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