A Clinical Significance Criterion Is Essential for Diagnosing Subthreshold Depression

To the Editor: In the March 2010 issue of the *Journal*, Jerome C. Wakefield, Ph.D., D.S.W., et al. (1) examined the redundancy thesis of the DSM-IV clinical significance criterion for major depression. The authors highlighted that the introduction of a clinical significance criterion does not meaningfully alter the prevalence rates of major depression, regardless of whether a clinical significance criterion with a low or high threshold is used. Furthermore, they concluded that the use of a clinical significance criterion for subthreshold depression is questionable, since "virtually all individuals reporting extended sadness also reported significant distress" (1, p. 302).

However, the conclusions for subthreshold depression were drawn on the basis of a questionable definition of clinical significance. Dr. Wakefield et al. (1) defined *clinically significant* distress or impairment as reporting *some* distress or impairment, which constitutes a low threshold for clinical significance. Different from major depression, clinical significance is not already an inherent part of the symptom cluster of subthreshold depression because of the low number of symptoms needed for the diagnosis. Hence, the low threshold of clinical significance conflicts with the purpose of a clinical significance criterion to reduce the risk of pathologizing human behavior. Using data of a general population survey, one recent study (2) demonstrated that the prevalence rates of subthreshold depression based on a clinical significance criterion with a low threshold (Munich-Composite International Diagnostic definition of clinical significance) were approximately equal to those obtained by using a cut-off score of 49 on the Short Form-36 Mental Component Summary score. Considering that a Mental Component Summary score of 50 represents the mean score of the general population, a low threshold of the clinical significance criterion seems inappropriate. It is crucial to define a threshold for clinical significance, which distinguishes persons whose level of distress reflects common human behavior from persons whose level of distress justifies a subthreshold diagnosis (2–4).

Using a higher threshold, Dr. Wakefield et al. (1) showed that 43.5% of all respondents who reported non-major depression sadness did not report severe distress. This high reduction of subthreshold cases by using a higher threshold for clinical significance corresponds with the aforementioned study (2), which highlighted that only 26.5%–61.1% of subthreshold diagnoses remain valid, if any clinical significance criterion is used in addition to a symptom count. Thus, the risk of pathologizing the general population is significantly reduced when a clinical significance criterion is taken into account. Diagnosing subthreshold depression is therefore a question of an appropriate threshold rather than a question of whether or not a clinical significance criterion is necessary (2–4).

References

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The author reports no financial relationships with commercial interests.

This letter (doi: 10.1176/appi.ajp.2010.10030398) was accepted for publication in April 2010.

Reply to Baumeister Letter

To the Editor: Dr. Baumeister has argued that in diagnosing subsyndromal depression, raising the distress threshold of the clinical significance criterion substantially reduces prevalence, preventing false positive diagnoses of normal distress (1). In his letter, he observes that our article's seemingly contrary finding that the clinical significance criterion's distress component had little impact on subsyndromal diagnosis was because of the very broad DSM-IV-based criterion of the National Comorbidity Survey Replication. Moreover, we too reported that higher distress thresholds may eliminate many cases. Unlike the redundancy of DSM-IV's clinical significance criterion with major depression symptoms, a high-threshold clinical significance criterion is not redundant with subsyndromal depression's more limited symptoms.

Further analysis supports the contention that raising clinical significance criterion distress thresholds substantially reduces subsyndromal depression prevalence. The National Comorbidity Survey Replication liberally allowed positive answers to any of four questions to establish distress, and the threshold was "moderate/sometimes." Our analysis included all non-major depression sadness cases (N=817), a heterogeneous mix. To more closely examine Dr. Baumeister's claim, we reanalyzed the data, including only respondents reporting sadness plus between one and three additional symptoms (N=241), using one-item criteria. For the item, "severity of emotional distress during sad episode," moving the threshold from "moderate" to "severe" reduced the rate of prevalence in the sample from 85% to 34% (if "very severe," to 7%). Using the more stringent item "emotional distress so severe could not carry out activities," moving the threshold from "sometimes" to "often" reduced the rate of prevalence from 21% to 5%.

How thoroughly such increased thresholds eliminate false positives remains uncertain because the symptoms' context is ignored. Even severe distress after major losses may not indicate mental disorder. But, context aside, we agree with Dr. Baumeister's contention that higher subsyndromal depression distress thresholds substantially impact prevalence and plausibly help to fix a serious false positives problem.

If this conclusion is correct, then proposed DSM-5 criteria for "depressive conditions not elsewhere classified" must be reconsidered. The proposal allows diagnosis of subsyndromal depression (sadness and one or more other symptoms lasting 2 weeks) that causes distress or role impairment. No dis-

tress threshold is specified (even mild distress qualifies), and symptom intensity thresholds are waived. This is considerably broader than the National Comorbidity Survey Replication/DSM-IV clinical significance criterion. Our analysis indicates that depending on the item used, between one-third and one-twentieth of subsyndromal depressions satisfy a higher threshold clinical significance criterion distress component, a more plausible approach to diagnosis of sadness with minimal accompanying symptoms in our view.

Consequently, the validity of DSM-5 subsyndromal depression criteria could be increased by requiring, for example, "persistent severe distress, persistent frequent disruption of normal activities, or other indicators of pathological dysfunction." Those suffering from intense sadness should be offered help, but misdiagnosing normal sadness as a disorder can lead to the wrong kind of help.

Reference

1. Baumeister H, Morar V: The impact of clinical significance criteria on subthreshold depression prevalence rates. Acta Psychiatr Scand 2008; 118:443–450

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The authors' disclosures accompany the original article.

This letter (doi: 10.1176/appi.ajp.2010.10030398r) was accepted for publication in April 2010.

Disguised Depression Deserves a Diagnosis

TO THE EDITOR: Dr. Wakefield et al. (1) examined the impact of clinical significance criteria for major depression on the occurrence of false positives. I have a related but different concern. While I am not aware of any data on the frequency with which this occurs, we all know of tragic incidents in which people who manifest no outward signs of depression commit suicide. Not all of these individuals are depressed, but some are. Some high-functioning people are able to present a completely normal face to the world, kiss their mates and children goodbye in the morning, smile at their co-workers, complete their tasks, and then take an overdose or hang themselves. How will we and DSM-5 address the reality of very depressed people who exhibit no outward signs of social withdrawal, inability to concentrate (though they may feel they cannot), changes in appetite (though they may have no appetite), loss of energy, or sadness?

Reference

1. Wakefield JC, Schmitz MF, Baer JC: Does the DSM-IV clinical significance criterion for major depression reduce false positives? Evidence from the National Comorbidity Survey Replication. Am J Psychiatry 2010; 167:298–304

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The author reports no financial relationships with commercial interests.

This letter (doi: 10.1176/appi.ajp.2010.10030391) was accepted for publication in April 2010.

Reply to Stotland Letter

TO THE EDITOR: Our article revealed the ineffectiveness of DSM-IV's clinical significance criterion in eliminating major depression false positive diagnoses, suggesting that further efforts are necessary. Dr. Stotland eloquently reminds us that further efforts are also necessary regarding false negatives. She observes that some depressed individuals mask their symptoms, and thus do not appear depressed, yet may be suicidal. However, the described patient satisfies major depression diagnostic criteria, and thus would not logically be a false negative.

Rather, the problem is epistemological, and potentially tragically so. False positive and false negative concerns are complementary in depending on optimally locating the boundary between normality and disorder, but they pose very different challenges. Dr. Stotland's example illustrates how even the loosest diagnostic criteria will not identify individuals whose symptoms are invisible to clinicians and intimates, nor will such criteria bring them into treatment against their will, and community screening will not necessarily help when individuals are inclined to hide their symptoms.

Human beings are adept at masking their feelings when motivated by shame, fear, pride, social desirability, or resoluteness in pursuit of a goal (e.g., suicide). Moreover, cross-cultural differences in emotional "scripts" and gender roles can yield widespread masking of feelings. Dr Stotland's example underscores the crucial clinical importance of a trusting therapeutic alliance and sensitivity to the patient's concerns and defenses, enabling the reluctant patient to communicate with us. No symptom checklist can substitute for the diagnostic importance of this relationship.

Those needing but not seeking our help, as in Dr. Stotland's example, pose a public health and prevention challenge. The ready availability of help and the acceptability of seeking it must be widely disseminated in various subcultures.

However, to return to the false positives problem, despite attempts to destigmatize mental disorder, efforts to link reluctant individuals with help may not be best served by framing all intense human distress as a medical disorder, but rather by recognizing and accepting the varieties of normal human response and suffering. Dr. Stotland's urgent challenge to detect the seemingly undetectable must not mislead us to justify extraordinarily expansive diagnostic or screening criteria that encompass everyone so that we miss no one, undermining the profession's credibility. The attempt to avoid false negatives is not well served by abandoning efforts to eliminate false positives.

Finally, as Dr. Stotland observes, many suicides do not result from major depression, nor is there any evidence for the prevalence of the particular type of example she describes. Such affects as anxiety, shame, or rage as well as impulsive reactions to distress or the effects of substance intoxication may be potent triggers of suicidal behavior in some individuals. Moreover, there are also rational deliberative or culturally sanctioned decisions to end one's life. This variety is reflected in the DSM-5's useful proposal for a suicide risk assessment scale that would routinely be applied across diagnostic categories.

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