

Review

GENERALIZED WORRY DISORDER: A REVIEW OF DSM-IV GENERALIZED ANXIETY DISORDER AND OPTIONS FOR DSM-V

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Background: Generalized anxiety disorder (GAD) has undergone a series of substantial classificatory changes since its first inclusion in DSM-III. The majority of these revisions have been in response to its poor inter-rater reliability and concerns that it may lack diagnostic validity. This article provides options for the revision of the DSM-IV GAD criteria for DSM-V. **Method:** First, searches were conducted to identify the evidence that previous DSM Work Groups relied upon when revising the DSM-III-R GAD and the overanxious disorder classifications. Second, the literature pertaining to the DSM-IV criteria for GAD was examined. **Conclusions:** The review presents a number of options to be considered for DSM-V. One option is for GAD to be re-labeled in DSM-V as generalized worry disorder. This would reflect its hallmark feature. Proposed revisions would result in a disorder that is characterized by excessive anxiety and worry generalized to a number of events or activities for 3 months or more. Worry acts as a cognitive coping strategy that manifests in avoidant behaviors. The reliability and validity of the proposed changes could be investigated in DSM-V validity tests and field trials. *Depression and Anxiety 0:1–14, 2010.* © 2010 Wiley-Liss, Inc.

Key words: DSM-V; GAD; worry disorder; classification; diagnostic criteria; overanxious disorder

STATEMENT AND SIGNIFICANCE OF THE ISSUES

Worry (n), a troubled state of mind arising from the frets and cares of life; harassing anxiety or solicitude.^[1]

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Generalized anxiety disorder (GAD) is a chronic and impairing disorder, independent of its substantial comorbidity with other mental disorders.^[2–8] Although it shares some risk and clinical similarities with other internalizing/emotional disorders,^[9] it can be distinguished from these disorders.^[10] The classification has thus progressed beyond treating GAD as a residual category or the “confusing stepchild among the anxiety disorders” as it was in DSM-III.^[11,12] DSM-IV-defined GAD is not a trivial disorder.

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Despite this, the validity of the diagnosis has been questioned because some individuals experience GAD-like symptoms and significant distress, and appear to warrant a clinical diagnosis, but they do not meet the DSM-IV GAD criteria.^[13] The reliability of the GAD diagnosis could also be improved,^[14] although the same could be said about all diagnoses. What is important, however, is that the reliability of GAD has increased since earlier classifications^[15] when DSM-III-defined GAD was one of the least reliable Axis I disorders,^[16] and as defined in DSM-III-R, it demonstrated the lowest inter-rater reliability among the anxiety disorders: current GAD κ ranged from .53^[17,18] to .56.^[19] Some reports now indicate that GAD is as reliable as depression.^[13] Would refining the DSM-IV criteria or substituting new criteria in DSM-V, increase the validity and reliability of this diagnostic classification further?

In comparison to the adult DSM-IV GAD diagnosis, far less is known about the validity and reliability of the diagnosis in children and adolescents. GAD was first diagnosed in youth in DSM-IV based on consensus judgment that subsuming DSM-III-R-defined over-anxious disorder (OAD) within DSM-IV-defined GAD would reflect the developmental continuum of the disorder.^[20–22] The DSM-IV criteria used to identify GAD in youth are similar to the adult criteria. The classification requires excessive, difficult-to-control anxiety and worry about a number of activities or events for 6 months or more but in contrast to adult GAD, childhood GAD requires one rather than three associated symptoms (see Table 1 for DSM-IV GAD criteria).^[21] Before DSM-IV it was unclear whether the DSM-IV diagnosis would identify the same patients as DSM-III-R-defined OAD. Has this nosological relationship since been clarified?

This article reviews the rationale for revisions made to the GAD criteria in DSM-IV, examines the data supporting those revisions, and makes preliminary recommendations for the GAD DSM-V criteria. A separate review currently in progress examines the risk factors and clinical features of GAD.^[10] The options presented in these reviews are based on reviews of the published literature. Therefore, they are strictly preliminary and do not reflect any definitive decision making on the part of the DSM-V Anxiety, Obsessive-Compulsive Spectrum, Posttraumatic, and Dissociative Disorders Work Group. Decisions will ultimately be based on the existing literature in combination with secondary data analyses, field trials, and group discussions. As a result, these recommendations are subject to change.

SEARCH METHODS

The Annotated Listings of Changes in each DSM,^[12,20,21] the DSM-IV Sourcebooks,^[23–25] the DSM-IV Options Book,^[26] and the manuscripts relied on and/or published by previous reviewers of the GAD

TABLE 1. DSM-IV criteria for generalized anxiety disorder

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- A. Excessive anxiety and worry (apprehensive expectation), occurring more days than not and for at least 6 months, about a number of events or activities (such as work or school performance)
 - B. The person finds it difficult to control the worry
 - C. The anxiety and worry are associated with three (or more) of the following six symptoms (with at least some symptoms present for more days than not for the past 6 months). Note: only one item is required in children
 - (1) restlessness or feeling keyed up or on edge
 - (2) being easily fatigued
 - (3) difficulty concentrating or mind going blank
 - (4) irritability
 - (5) muscle tension
 - (6) sleep disturbance (difficulty falling or staying asleep, or restless unsatisfying sleep)
 - D. The focus of the anxiety and worry is not confined to features of an Axis I disorder. Eg., the anxiety or worry is not about having a panic attack (as in panic disorder), being embarrassed in public (as in social phobia), being contaminated (as in obsessive compulsive disorder), being away from home or close relatives (as in separation anxiety disorder), gaining weight (as in anorexia nervosa), having multiple physical complaints (as in somatization disorder), or having serious illness (as in hypochondriasis), and the anxiety and worry do not occur exclusively during posttraumatic stress disorder
 - E. The anxiety, worry, or physical symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.
 - F. The disturbance is not due to the direct physiological effects of a substance (e.g. a drug of abuse, a medication) or general medical condition (e.g., hyperthyroidism) and does not occur exclusively during a mood disorder, a psychotic disorder or a pervasive developmental disorder
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diagnosis were consulted for details of the DSM-III to DSM-IV GAD criteria revisions. The proceedings and/or monographs of the preparatory conference series for DSM-V, particularly the *Refining the Research Agenda: Comorbidity of Depression and Generalized Anxiety Disorder* conference were also used.

For research published since the release of DSM-IV, computer database searches were conducted using the SCOPUS and MEDLINE search engines for English language articles published from January 1990 to June 2009. GOOGLEBOOK searches were also conducted. Search terms included *generalized anxiety disorder*, *generalized anxiety disorder*, *GAD*, *overanxious disorder*, *OAD*, and *worry*. The reference lists of the identified manuscripts and books were also reviewed manually.

RESULTS/OPTIONS FOR GAD IN DSM-V

THE RELATIONSHIP BETWEEN DSM-III-R-DEFINED OAD AND DSM-IV-DEFINED GAD

Since subsuming the DSM-III-R OAD diagnosis within the DSM-IV GAD diagnosis, clinical and

epidemiological studies have provided conflicting evidence about the overlap of the two diagnoses. Kendall and Warman^[27] in a referred clinical sample using the Anxiety Disorders Interview Schedule (ADIS) Child version ($N = 40$; $M = 11.13$ yrs) reported that there was 98% agreement on parental reports and 93% agreement on children's self-reports of the DSM-III-R-defined OAD and DSM-IV-defined GAD. Tracey et al.^[28] showed that all children attending a specialist anxiety clinic with a clinical level diagnosis of DSM-III-R OAD would also satisfy criteria for DSM-IV GAD when a diagnosis is based on the aggregate of parent and child reports of symptoms (i.e. using the "or" rule) on the ADIS for DSM-IV, Lifetime version (ADIS-IV-L) ($N = 62$; $M = 12.8$; $SD = 3.18$). There was also complete diagnostic overlap between children with GAD and those with OAD. Epidemiological data, however, show discrepancies between the two diagnoses. In the Great Smoky Mountain Study (GSMS), which uses the Child and Adolescent Psychiatric Assessment and the "or" rule for assigning a diagnosis, Costello et al.^[29] report that by age 16 182 children (11.6% of sample) had either DSM-III-R-defined OAD, DSM-IV-defined MDD, and/or GAD. However, only 23.5% of those with GAD or OAD had the disorders concurrently. Children who meet OAD or GAD diagnostic criteria may also have different longitudinal trajectories. Bittner et al.^[30] in the GSMS report that childhood OAD predicts adolescent OAD, panic attacks, and DSM-IV-defined MDD and conduct disorder, whereas childhood GAD only predicted, unexpectedly, adolescent conduct disorder. It is noteworthy that in this study only 14% of cases with OAD also satisfied childhood GAD criteria and that there were no associations between childhood OAD and adolescent GAD and vice versa. Although Pine et al.^[31] in their prospective longitudinal epidemiological study did not directly compare OAD and GAD, their reports are consistent with Bittner et al. showing that adolescent OAD predicted a range of adult psychopathological outcomes (social phobia, MDD, panic and GAD). In contrast to the Bittner et al.'s study that overall used a younger sample, Pine et al. found adolescent OAD to be related to adult GAD.

DSM-IV-defined GAD in youth has fair to excellent test-retest reliability depending on which informant and which interview are used.^[32-34] Similar to other childhood disorders the diagnostic agreement between informants (i.e., parent and child) ranges from poor to fair, although symptom-level agreement is typically better.^[28,35-37] Few data had accumulated on DSM-III-R-defined OAD before it was incorporated within DSM-IV-defined GAD,^[38] and there has been limited investigation of the diagnostic thresholds of DSM-IV-defined GAD in youth. Thus, this review at times makes necessary generalizations from adult studies to children. This is a limitation.

In summary, it appears that there is some degree of relatedness between OAD and GAD; nonetheless,

more research is needed on whether the DSM-III-R criteria for OAD and the DSM-IV criteria for youth with GAD are identifying the same disorder. Subsequent reference to children and adolescents will thus focus on DSM-IV-defined GAD (as DSM-IV does not include OAD).

DSM-IV CRITERION A: THE NATURE, FOCUS, AND DURATION OF ANXIETY AND WORRY

Anxiety and worry (apprehensive expectation) about a number of future events or activities were introduced as the hallmark features of GAD in DSM-III-R, with the result that GAD was no longer a residual diagnosis.^[20,39-41] Worry is the cognitive component, as distinct from the physiological symptoms, of anxiety. There appears to be consensus that worry is an avoidant coping strategy that is negatively enforced by reductions in patients' worry. This reduces emotional reactivity in the short term but because patients do not process their distress other than in the abstract they experience ongoing distress and continue to use worry to reduce this distress.^[42-47] The concept of cognitive avoidance derives from Borkovec's early work on the nature of worry, suggesting that the worries experienced by GAD patients are predominantly verbal-linguistic rather than imagery based^[48,49] and that verbally based cognitions are associated with less arousal when experiencing threatening cues than are imagery-based cognitions.^[49-51] The hypothesized function of GAD patients' verbally based cognitions is to minimize the autonomic arousal they would otherwise experience if threatening stimuli were processed in imagery.^[52,53]

Borkovec proposes that these avoidant strategies are implicit, whereas others purport that worrying can be an explicit coping mechanism,^[43,47] including the catastrophic "what ifs...?" that are commonly seen when treating GAD. Active suppression of worries, substitution of neutral or positive thoughts for worries, use of distraction techniques to interrupt their worries, and the active avoidance of situations that cause distress are also thought to be strategies used by GAD patients.^[44,47] Cognitive avoidance does show some symptom specificity in adults with clinical worry when compared to panic symptoms^[54] and also decreases with effective CBT treatment.^[55,56] In children and adolescents there has been little investigation into the use of avoidant strategies but Gosselin et al.^[57] did show that nonclinical adolescents who experience high worry ($N = 158$, Penn State Worry Questionnaire (PSWQ) $M(SD) = 61.2(6.2)$) engage in more cognitive avoidance strategies than those experiencing moderate worry ($N = 187$, PSWQ $M(SD) = 43.8(2.1)$). Avoidant strategies significantly predicted worry level, with avoidance of triggers, thought substitution, distraction, and thought suppression accounting for 19% of the variance in the youths'

worry scores. Positive beliefs about worry explained a similar amount of variance (14%) as these avoidant strategies.

If clinical and research evidence support retaining a specific component of anxiety—worry when it is focused on multiple events or activities (discussed below)—as the defining feature of GAD in DSM-V, should the disorder be renamed to more clearly convey this central concept of worry? Options include names like “generalized worry disorder,” “major worry disorder,” or “pathological worry disorder.” Indeed, the prominence of worry in this disorder has led GAD patients to often be referred to as “pathological” or “chronic” worriers. The term pathological is used here in the sense that it distinguishes normal and disordered states, but worry is not specific to GAD. People with other anxiety disorders, mood disorders, and no disorders at all, also worry. Thus, how worry is identified clinically, how it is formally defined, and the nature of its associated features will influence the reliability and validity of the revised classification. DSM-IV GAD criteria presume that defining worry as excessive, generalized to multiple activities or events, difficult-to-control, and chronic and disabling, establishes nosological boundaries that identify a reliable, valid, and clinically significant disorder. Evidence for each part of this definition is examined below.

Anxiety and worry that is excessive. Would changing the excessiveness criterion improve the psychometric properties of the GAD diagnosis? Pathological worry defined in terms of “excessiveness” may reduce the reliability and validity of the diagnosis. Excessiveness is an ambiguous term, and as Ruscio et al.^[58] noted there is no guidance on “what makes worry excessive?” and “who [should] determine if the worry is excessive?” Wittchen et al.^[59] used the University of Michigan Composite International Diagnostic Interview (UM-CIDI) structured interview in a clinical reappraisal of a subset of National Comorbidity Survey participants who endorsed all criteria for lifetime DSM-III-R GAD ($N = 24$) and those who reported 6 months or more in which they felt worried, tense, or anxious but did not satisfy all the other GAD criteria ($N = 12$). They found that 70% of those who endorsed all GAD symptoms did so at follow up and 58% of those who did not endorse all GAD symptoms again received a negative GAD diagnosis, corresponding to a κ of .53. However, if “unrealistic or excessive” worry was not required for a positive GAD diagnosis, this κ increased to .78. In the same study, excessive or unrealistic worry was also a primary source of discrepancy between GAD diagnoses based on the UM-CIDI and the SCID.^[59] In their reliability assessment of DSM-IV GAD using the ADIS-IV-L, Brown et al.^[13] reported that a dimensional measure of excessiveness would be more reliable than the current categorical criterion. In terms of validity, Ruscio^[60] reported that excessive and uncontrollable worry may be associated with severe worry rather than with GAD

per se. Slade and Andrews^[61] in their cross-classification study reported that although there is 98% agreement between DSM-IV and ICD-10 on negative GAD diagnoses, the two systems only agree on 41% of positive diagnoses. Seventy-two percent of those who endorsed all ICD criteria (including “prominent” worry) did not report excessive worry. This was the largest source of discrepancy between the two classifications.

If the excessiveness criterion were omitted from the GAD definition in DSM-V, the classification would continue to identify a group that experiences clinically significant distress or impairment as measured by endorsement of criterion E. However, the identified group would experience milder symptoms than if they were diagnosed by DSM-IV criteria (Australian National Survey of Mental Health and Well-Being 1997 (NSMHWB-1); National Comorbidity Survey–Replication (NCS-R)).^[58,61] This broader classification (i.e., including respondents who report either excessive or nonexcessive worry as having GAD) would also increase the number of children and adults with GAD by approximately 27 to 40% (NCS-R; Early Developmental Stages of Psychopathology (EDSP)).^[58,62] For example, in the NCS-R 12-month GAD would increase from 2.0 to 2.8%.

Although omitting the excessiveness criterion may increase the population that would satisfy the remaining GAD criteria, it would not substantially change the *type* of person identified as having GAD. People with excessive and nonexcessive worry who meet all other GAD criteria are similar in terms of socio-demographics (NCS-R),^[58] distribution of severity scores (constructed from indices of uncontrollability, impairment, and distress) (NCS-R),^[58] treatment seeking (EDSP),^[62] and familiarity (NCS-R).^[58,62] Furthermore, the variously defined GAD groups have substantial lifetime comorbidity, although for some disorders GAD with “excessive” in the criteria set has significantly higher comorbidity odds ratios than GAD without this term in its criteria set (NCS-R; EDSP).^[58,62] GAD that includes “excessive” also begins earlier in life and is more persistent than nonexcessive GAD (NCS-R).^[58] Interestingly, excessiveness does not clarify the diagnostic border with MDD, perhaps the most challenging boundary condition for GAD, in either the NCS-R or the EDSP (e.g., 12-month MDD is significantly associated with excessive and non-excessive GAD).^[58,62]

DSM-V OPTIONS FOR THE EXCESSIVENESS REQUIREMENT

Anxiety and worry (apprehensive expectation) focused on multiple future activities or events that is extreme or disproportionate to those events is the defining feature of GAD and distinguishes GAD from normal worry and other anxiety and mood disorders. Although the excessiveness descriptor reflects the status quo there are no data or clinical consensus in the

literature that support identifying another aspect as the *core* feature of the diagnosis. The data accumulated since the publication of DSM-IV shows that, although omitting the excessiveness requirement from DSM-V would identify people with similar characteristics to DSM-IV in terms of socio-demographics and comorbidity, it would increase the prevalence of the disorder substantially (at least in community samples), and it would identify a milder form of the disorder. Although excessiveness is the largest source of discrepancy between DSM-IV and prominent worry in ICD-10, this is not a problem with DSM-IV GAD *per se*.

There is limited evidence that removing the excessiveness criterion would increase reliability. Due to its traditional connection with GAD, it may be of more benefit to the classification if further guidance is given as to what excessive means and who (i.e., the patient, a significant other, the clinician) is to determine whether the worry is excessive. "Excessiveness" could, of course, be operationalized by observable outcomes (i.e. amount of time per day spent worrying; degree of interference with concentration on nonworry tasks; behaviors connected with the worry such as checking) as is currently done for symptoms of other emotional disorders such as MDD and obsessive-compulsive disorder (OCD).

Anxiety and worry about a number of events or activities. Adults experiencing GAD worry more pervasively, and about more future events and activities, than adults without GAD, and they tend to worry more about interpersonal/family issues and minor day-to-day activities rather than problem-based activities associated with work and/or school.^[40,41,63] Children experiencing GAD symptoms also worry more pervasively than children experiencing symptoms of other anxiety disorders and nonanxious controls.^[28,64-66] They do however worry about the same events/activities, including personal health, family, and school, as nonanxious children but at a greater intensity.^[67-69]

Reports since the release of DSM-IV are consistent with these findings upon which the DSM-IV Anxiety Work Group adult criteria reviews relied. Roemer et al.^[70] examined separately a clinical group with a primary GAD diagnosis ($N=97$ GAD; 48 controls) and a college group ($N=137$ GAD; 120 controls). Both GAD groups reported more worry domains (i.e., more generalized worry) than nonanxious controls and worried more about family/interpersonal and miscellaneous topics such as minor matters and routine daily activities. GAD patients also worried about more topics, particularly people/relationships, finances, religion/politics/environment, and "daily hassles" than those with social phobia.^[71] Older patients with GAD ($N=36$, mean age = 68.4 years, $SD=8.2$) also report more pervasive worry than those experiencing sub-threshold-anxiety (defined as respondents who sought treatment for anxiety but who did not satisfy full DSM-IV criteria for any disorder, $N=22$) particularly about minor matters, finances, social/interpersonal matters,

and their personal health. This sub-threshold group, however, did report more generalized worry than nonanxious controls ($N=32$).^[72] Diefenbach et al.^[73] reported slightly discrepant findings to this, suggesting that older GAD patients worry more than controls but do not worry about significantly different topics.

Others have indicated that worriers often couch their worries in terms of personal ineptness.^[74] Vasey and Borkovec^[75] conducted content analyses on all steps from "catastrophizing" interviews in which participants were asked to state all the negative consequences of areas of worry (e.g., If I received a negative evaluation at work, then ...). Worriers generated proportionally more "failure/ineffectiveness" content than nonworriers. These results were consistent with a follow-up study by Davey and Levy,^[76] in which trait worry scores correlated positively with both the number of catastrophizing steps generated and independent judges' ratings of the content as "feelings of personal inadequacy." Hazlett-Stevens and Craske^[77] replicated this in their study of content of catastrophizing across six different domain areas of threat among controls and analog GAD participants.

DSM-V OPTIONS FOR "A NUMBER OF EVENTS OR ACTIVITIES"

There is consensus as to the pervasiveness of worry associated with GAD in children and adults. Individuals experiencing GAD worry about more activities and events than nonanxious controls and people with some other anxiety disorders. The DSM-IV examples of the worry domains appear accurate but inserting "family, health, and finances" would better reflect the events that are of most concern to GAD patients.

The Duration of the anxiety and worry. The duration criterion of DSM-IV-defined GAD is a large source of discrepancy in the test-retest reliability of diagnoses, with Wittchen et al.^[14] reporting that the κ for current GAD of .45 would increase to .70 if only 1-month rather than the 6-month duration was required (i.e. the endorsement of the stem question "anxious worrying for 1 month or longer" was high). Recalling whether or not the worry has been present most days for 6 months (or more) is difficult, whereas recall over a shorter period may be easier, particularly for children. The decision whether to maintain or change the duration threshold of GAD is, similar to the other diagnostic criteria, a balance of evidence and policy considerations. In the developed countries from the World Mental Health Surveys (WMHS), if the threshold was reduced to a 3- or 1-month duration, the 12-month prevalence of GAD would increase from 1.7% (DSM-IV) to 2.2 and 3.2%, respectively. Alternatively, if the threshold were increased to 12 months, the 12-month prevalence would decrease to 1.3%. (WMHS; see also NCS-R).^[78-80] When the duration was reduced to 3 months in the second Australian NSMHWB (which used the same assessment instrument

as the WMHS) 13% more patients reported seeking treatment because of their anxiety and worry as compared with the 29% increase in the general population prevalence across the WMHS.^[81]

A number of studies have shown that a lower duration threshold (e.g., 1 month, 3 months) would identify respondents with similar symptom severity and clinical impairment to the current 6-month threshold (WHO Psychological Problems in Primary Care; NCS-R; Zurich Cohort Study).^[79,82,83] Requiring a longer duration requirement (e.g., 12 months), however, would identify respondents with more severe and impairing symptoms than are found in DSM-IV GAD (WMHS).^[78] Moreover, variations in the duration threshold would not substantially influence the type of person identified in DSM-V in terms of demographics (ECA; NCS-R; Zurich Cohort Study);^[79,83,84] age of onset (WMHS);^[78] familial risk of GAD (Virginia Twin Registry; NCS-R; EDSP);^[77,85,86] or comorbidity profiles (ECA; Zurich Cohort Study; WMHS; EDSP).^[62,78,83,84] Symptom endorsement profiles are also similar between DSM-IV-defined GAD and GAD of 3–5 month duration (German National Health Interview and Examination Survey).^[87]

The aforementioned data suggest that the DSM-V classification would continue to identify a clinically significant generalized anxiety syndrome even if the duration threshold were lowered. Yet this must be balanced with other considerations. A reduced duration threshold could also face similar criticisms as the 1-month DSM-III threshold, which reduced the discriminant validity of GAD relative to ordinary anxious reactions to life events^[88] and did not reflect the chronic course of GAD.^[89] However, these critiques of the lower threshold were made at a time when GAD lacked a defining feature. It is possible that the classification has now progressed such that the other symptom thresholds compensate for any possible loss of discriminant validity from reducing the duration threshold.

DSM-V OPTIONS FOR THE DURATION OF GAD ANXIETY AND WORRY

Given that the GAD diagnosis now has worry as a defining feature and a lower duration threshold would largely recognize the same *type* of patient experiencing similar distress and impairment as those with DSM-IV-defined GAD, it is recommended that the duration requirement of GAD in DSM-V be 3 months. Reducing the duration threshold to 3 months (or more) could increase the prevalence of GAD and attract similar criticisms to the DSM-III 1-month threshold. Nevertheless, this shorter duration requirement reflects some of the chronicity of the disorder while increasing the validity of the diagnosis by recapturing clinically significant cases. The shorter duration may also increase diagnostic reliability by

decreasing discrepancies in informant recall, although the influence on reliability remains to be tested.

Option for Criterion A of DSM-V GAD

A: The person experiences excessive anxiety and worry (apprehensive expectation):

- (a) about two (or more) domains of activities or events (for example, domains like family, health, finances, and school/work difficulties);
- (b) which occurs on more days than not;
- (c) for 3 months (or more).

DSM-IV CRITERION B: DIFFICULT-TO-CONTROL WORRY

The perception of control over worry is negatively associated with anxiety, that is, the more control an individual perceives over their worry the fewer anxiety symptoms they report.^[90–92] Yet surprisingly few data are available regarding the importance of Criterion B to the GAD diagnosis. From clinical experience, the notion of “difficult-to-control” may be difficult for children to understand and it does not appear that children experiencing other GAD symptoms actually attempt to stop their worry. Consequently, reliance on children’s self-reports alone may result in underdiagnosis notwithstanding that some children and adolescents will recognize that their worries are difficult-to-control. It may be that before children are able to attempt worry control, they require some higher meta-cognitive capacity that allows them to reflect on their worry and identify that it may be out of control. It is unclear whether children who have not reached formal operations have the capacity to do this, and if they do, it may reflect a particularly severe form of GAD. Consistent with this supposition, Tracy et al.^[28] in their comparison of DSM-III-R OAD and DSM-IV GAD criteria show that parental report of uncontrollability of worry correlated higher with the clinician’s severity of the child’s symptoms and level of distress/impairment ($r = .62$ vs. $r = .87$). They concluded that “children may have difficulty articulating the concept of uncontrollability, and therefore parent report of uncontrollability might be especially important”, p 412.

A number of cognitive models address the role that perceived and actual differences in the ability to control worry play in GAD. For example, the meta-cognitive model espoused by Wells^[93,94] holds that although individuals with a variety of anxiety disorders believe worry is a useful coping strategy (positive beliefs about worry), individuals only with GAD have negative beliefs about worry (i.e., “worry about worry”), such as that their worry is uncontrollable and/or dangerous.^[95] Ruscio and Borkovec^[96] used the Meta-Cognitions Questionnaire^[97] to compare beliefs about worry held by college students who met GAD criteria with a group of non-GAD high worriers ($N = 30$ GAD; 30 non-GAD high worriers). Despite comparable worry

severity, the two groups differed in their perception of their worry; the GAD high worriers were significantly more likely to regard their worry as harmful, dangerous, or out of control. In contrast, both high-worry groups reported positive beliefs about their worries. Ruscio and Borkovec also compared the non-GAD high worriers to a group of nonanxious controls used in the validation of the questionnaire. Slightly inconsistent with the meta-cognitive model, they found that the negative belief that worry is uncontrollable and dangerous was not unique to the GAD group: GAD worriers were more likely to consider their worry as uncontrollable and dangerous than non-GAD high worriers, who reported their worries to be more uncontrollable and dangerous than nonanxious controls. Finally, Ruscio and Borkovec examined uncontrollable worry experimentally and found that GAD and non-GAD high worriers differed in their control over worry following a worry induction, although group differences dissipated quickly. Initial research suggests that the perception of control over worry may be dimensional rather than providing a categorical distinction between GAD worriers and controls, but more evidence is needed.

Recent research shows that if the difficult-to-control criterion were omitted in DSM-V, it would have little impact on the identified cases (NSMHWB-2; EDSP).^[62,81] For instance, in the NSMHWB-2, a representative Australian community sample, a more broadly defined GAD that includes both difficult and nondifficult to control worry would increase lifetime prevalence in treatment-seeking populations from 4.21% for DSM-IV GAD to 4.57%.

The majority of the variance that the difficult-to-control criterion contributes to the classification may be explained by the excessiveness criterion: Could a worry be excessive but still controllable? Clinical opinion would suggest not. In support of this conclusion, in the EDSP only ~4% of respondents who satisfied all other DSM-IV criteria for GAD reported that their worry was excessive but was still controllable.^[62] There is no evidence on whether removing the difficult-to-control criterion would have the same effect in clinical samples as it does in the community.

If “difficult-to-control” is *not* redundant with “excessive,” does it help distinguish GAD from other anxiety and mood disorders and from healthy controls? Unfortunately, there are limited data on the discriminant validity of the difficult-to-control criterion but Hoyer et al.^[71] showed that GAD patients find their worry more difficult-to-control than patients with social phobia and nonanxious controls.

DSM-V OPTION FOR CRITERION B: DIFFICULT-TO-CONTROL WORRY IN GAD

There are surprisingly little data regarding the difficult-to-control criterion and thus, it was difficult to determine the utility of retaining or omitting the

criterion from the GAD diagnosis in DSM-V. With parsimony in mind, given that there are nationally representative epidemiological data consistently showing that the difficult-to-control criterion may be unnecessary if the other GAD criteria are retained, there are sparse data to support retaining this criterion in DSM-V. The effect of omitting, or changing this criterion needs to be examined in clinical samples.

DSM-IV CRITERION C: THE ASSOCIATED SYMPTOMS OF GAD

Revisions to the associated symptom criterion have previously relied on the rationale that the items most frequently endorsed by patients with GAD should be retained and those items least frequently endorsed should be omitted from the classification.^[39,88,98] The removal of the autonomic hyperarousal symptoms from DSM-III-R to DSM-IV was also based on psychophysiological data comparing patients with GAD to nonanxious controls.^[99,100] Subsequent research has shown that the associated symptom items retained in DSM-IV are among the most highly endorsed from the DSM-III-R list in children and adults,^[28,34,101–104] though it has been reported that “nausea, diarrhea, or other abdominal distress” are also highly endorsed by some adults.^[103,104] Of the retained symptoms, parents tend to report more somatic symptoms than their children.^[105]

The DSM-III-R motor tension, and vigilance and scanning symptom clusters also distinguish primary GAD from other primary anxiety disorders but they did not distinguish GAD from primary MDD ($N = 390$ total; 73 principal GAD diagnoses). Nevertheless patients with GAD did endorse significantly greater autonomic hyperactivity than MDD patients.^[106] Although the latter symptom cluster may distinguish GAD from MDD, according to the rationales and evidence relied upon by earlier revisions, this would decrease the discriminant validity of the diagnosis with nonanxious respondents.

Although data post-DSM-IV predominantly supports the decision to retain the associated symptoms included in DSM-IV, Kubarych et al.^[104] queried whether this method alone provides a justifiable basis for omitting symptoms. They suggested that the least endorsed symptoms may reflect the most severe form of the disorder and will thus be lower in frequency (or at least distributed across the severity continuum). Kubarych et al. concluded that attempts to increase the discriminant validity of the associated symptoms criterion by reducing the number of symptoms^[39,88] was not successful, given that in a factor analysis MDD, panic disorder, specific phobia and alcohol dependence all loaded on the GAD symptom factor. The associated symptoms of GAD are also the second largest source of discrepancy between GAD in DSM-IV and ICD-10. Approximately half of the respondents who endorse all DSM-IV criteria would not satisfy ICD-10 criteria

because they did not endorse at least one of the four autonomic arousal symptoms.^[61]

The DSM-IV associated symptoms “restless or feeling keyed up or on edge” and “muscle tension” are specific to GAD. The others are not. For example, fatigue, difficulty concentrating, and sleep disturbance occur in major depressive episodes; and irritability and sleep disturbance occur in post-traumatic stress disorder. How many associated symptoms should be required? In children, requiring either the child or parent to endorse at least one symptom from the six DSM-IV symptoms increases the sensitivity and specificity of the diagnosis.^[28] In adults the change in threshold to three symptoms from six symptoms in DSM-III-R was adopted with little empirical support for the discriminant validity and utility of the change. Brown et al.^[106] evaluated this threshold and found it to be quite sensitive, with 98.6% of the positive DSM-III-R GAD patients also endorsing the DSM-IV three or more threshold. However, the specificity of the threshold was low in relation to principal diagnoses of other anxiety disorders (.307) and MDD (.071). When the threshold was increased to four from six symptoms, the specificity and thus discriminant validity also increased (.478), whereas sensitivity remained relatively stable (.973).

In representative community samples, reducing the number of associated symptoms required makes little difference for the prevalence of GAD. For example Ruscio et al.^[80] showed that requiring two rather than three symptoms had little effect on prevalence. Reducing it to one symptom had negligible further effect (EDSP).^[62] Although effects were small they were larger in children/adolescents than adults providing some, albeit limited, support for the associated symptom criteria with a threshold of one symptom in these younger cohorts. In the first Australian NSMHWB, deleting criterion C altogether increased the 12-month prevalence by 4.2%. The individual symptoms are endorsed by the majority of people with GAD (restless: 88%; keyed-up: 89%; fatigued: 79%; difficulty concentrating: 82%; irritable: 82%; and muscle tension: 59%. Data are available on request). If however, deleting them has little effect on the prevalence of the disorder there seems little point in retaining the nonspecific associated symptom criteria (i.e., fatigue, difficulty concentrating, sleep disturbance, and irritability). The symptoms which are specific and endorsed by most respondents with DSM-IV-defined GAD (i.e., restlessness or feeling keyed up or on edge, muscle tension), if retained could increase or at least maintain the discriminant validity of the criteria from other mood and anxiety disorders.

The core symptom of GAD is cognitive, and the DSM-IV-associated symptoms are cognitive, affective and physical manifestations of hypervigilance and tension. There appears to be consensus, as reviewed above, that worry is a cognitive avoidant mechanism but could the manifest behaviors (i.e., avoidance

behaviors) associated with these cognitions be identified? Could including these behaviors in DSM-V increase the reliability and the validity of the GAD diagnosis?

Given that worry appears to be used as an avoidant strategy particularly by adults and that this may be done explicitly, it is not surprising that these models—especially the cognitive avoidance, meta-cognitive, and intolerance of uncertainty models—propose that GAD patients have positive beliefs about their worries. However, positive beliefs about worry appear to be general markers of the anxiety disorders^[55,107] and of severe worry in the absence of GAD^[96] rather than specific markers of GAD, and so they may not have sufficient utility to be added to the associated symptoms criteria.

GAD patients may engage in avoidant behaviors because of an intolerance of uncertainty. This could result from their beliefs that uncertain situations and the implications thereof are “stressful and upsetting, that being uncertain about the future is unfair, that unexpected events are negative and should be avoided, and that uncertainty interferes with one’s ability to function.”^[47] Intolerance of uncertainty shows some symptom and diagnostic specificity. In nonclinical adolescent and adult samples it is positively related to worry^[108,109] and shows a stronger relationship with worry than with other anxious and depressive symptoms, although there is some overlap with depressive symptoms^[110,111] and there are reports of equally strong relationship with obsessive-compulsive symptoms.^[112] In their nonclinical adolescent sample, Laugesen et al.^[109] showed that compared to positive beliefs about worry and negative problem solving orientation, intolerance of uncertainty was the greatest predictor of the experience and severity of worry. In clinical samples, intolerance of uncertainty is more characteristic of GAD than other anxiety disorders,^[107] and in nonclinical respondents intolerance of uncertainty is related to worry more than depression.^[55] Patients with severe GAD also have a greater intolerance of uncertainty than those with milder forms of the disorder.^[113] Furthermore, intolerance of uncertainty can be modified and changes are associated with corresponding increases or decreases in worry.^[114] Increased tolerance of uncertainty also is associated with and typically precedes decreases in worry during treatment.^[115]

In addition to avoiding uncertain situations, patients with GAD are known to engage in checking behaviors. The term “checking” is used here tentatively because of its association with OCD. Nonetheless these behaviors can be differentiated across the two disorders in terms of the focus of the checking. Patients with OCD tend to focus their checking on objects, whereas GAD patients tend to focus their checking on relational situations and achievement.^[116] The focus of these behaviors may be particularly important in differentially diagnosing OCD and GAD in children. GAD

patients are also known to seek reassurance from others in response to their worries^[117] and use checking behaviors as an avoidant strategy.^[118] Reassurance was definitional for DSM-III-R OAD,^[20] and in our clinical experience excessive reassurance seeking is a particularly common characteristic of GAD in children. Moreover, GAD patients procrastinate; that is, they delay making decisions or behaving in certain ways a great deal more than would be expected and this can also be thought of in terms of the cognitive avoidance model of worry. It is difficult for GAD patients to make decisions because they could make the “wrong” decision and this is associated with negative emotions and hence should be avoided.

There are no data yet to inform where the threshold for this criterion should be set if specific behaviors are introduced in DSM-V as part of the GAD diagnosis or how it might best be operationalized. The option given below suggests that one or more avoidance behavior is reported but this is preliminary and the formal threshold will be informed by testing the proposed criteria.

DSM-V OPTION FOR THE ASSOCIATED SYMPTOMS OF GAD

The DSM-III-R symptoms retained in DSM-IV are the associated symptoms most frequently endorsed by GAD patients, but several are largely nonspecific to GAD. “Restless or feeling keyed up or on edge” and “muscle tension” are specific to the diagnosis and are also endorsed by most adult respondents with GAD and the former endorsed by most children and adolescents with GAD. If the nonspecific symptoms are omitted in DSM-V, it may increase the discriminant validity of the diagnosis particularly in relation to MDD, which has the largest symptom overlap with GAD. There is little evidence to support the current cutoff of three symptoms or to advocate an alternative threshold if all the DSM-IV associated symptoms were retained. Theoretical models of GAD suggest that the inclusion of criteria reflecting avoidant cognitive strategies in GAD and patients’ associated *behaviors* with worry may benefit the DSM-V classification. The impact of their inclusion on diagnostic reliability, validity, and utility of adding such criteria has yet to be established.

Option for Criteria B and C of DSM-V GAD

B. The anxiety and worry are associated with one (or more) of the following symptoms:

- (a) restlessness or feeling keyed up or on edge
- (b) muscle tension

C. The anxiety and worry leads to changes in behavior shown by one (or more) of the following:

- (a) marked avoidance of potentially negative events or activities
- (b) marked time and effort preparing for possible negative outcomes of events or activities

(c) marked procrastination in behavior or decision-making due to worries

(d) repeatedly seeking reassurance due to worries.

DSM-IV CRITERION E: CLINICAL SIGNIFICANCE CRITERIA

Slade and Andrews^[119] report that the clinical significance criterion for MDD and GAD reduces prevalence in community respondents (~20%) and identifies threshold cases who are more likely to consult mental health professionals, and who are more disabled than sub-threshold cases. In contrast, Zimmerman et al.^[120] show that in a psychiatric outpatient sample the clinical significance criteria reduced prevalence by only 2%. Although an “activity limitation” or clinical significance criterion may be appropriate as a precondition for any mental disorder, it is not inherent to the GAD phenotype in the same way as anxiety and worry are. As the inclusion of clinical significance criteria is being considered by the DSM-IV Impairment Work Group, a decision on its relevance to GAD will be deferred until the recommendations of that group are available.

DSM-IV CRITERIA D AND F: HIERARCHICAL EXCLUSION CRITERIA

There has been little examination of the importance of the hierarchical exclusion criteria in GAD adults and no study of their influence on childhood GAD diagnoses. It is likely that these hierarchies particularly Criterion F are conceptual remnants of GAD’s residual status in DSM-III. Given that other criteria have been introduced that establish the diagnostic independence of GAD, Criteria D and F may be of little importance to the DSM-V classification particularly Criterion F.

Many epidemiological studies that do not apply the hierarchical exclusion criteria have been able to identify differences between GAD and the other anxiety and mood disorders on external validating criteria.^[10] In one of the few direct examinations of the influence of Criterion F on caseness, Zimmerman and Chelminski^[121] compared patients with comorbid MDD and GAD; patients who experienced GAD only during the course of their depression (i.e., satisfied all GAD criteria except Criterion F); and patients with MDD but not GAD. The two GAD groups did not differ in terms of clinical or psychosocial correlates, or in their family history of anxiety, depressive, or substance-use disorders. Similarly, in their recent work Lawrence et al. show that the hierarchy imposed by this exclusion criterion with the mood disorders is obscuring the clinical features of GAD patients.^[122] Patients who reported GAD criteria except Criterion F and patients who experienced comorbid GAD/MDD were more severe, more neurotic and more impaired than patients who experienced MDD but not GAD. These findings suggest that the hierarchical exclusion criteria are

excluding patients from the GAD diagnosis who, in terms of correlates could be considered disordered. It may be that, in practice, this has caused the overuse of the MDD or the otherwise not specified categories. These findings provide some support for reconsidering the utility of the hierarchies imposed by criteria D and F.

IS GAD DIMENSIONAL?

The DSM provides thresholds for GAD but many have argued that disorders exist as dimensions of illness and do not stop existing at the cut-points provided by the DSM criteria.^[123] There is implicit evidence from the aforementioned epidemiological population studies that show that variations in some of the DSM-IV GAD criteria such as duration identifies largely the same *type* of respondent as a diagnosis using a variant thereof.

Structural studies of worry provide some support for a dimensional interpretation of GAD. Ruscio et al.^[124] investigated the latent structure of worry in a college sample ($N = 1,588$) and reported that worry exists on a continuum with low and high worriers falling at the extremes. Factor analyses typically find a one-factor solution underlying the PSWQ but there are others that identify a two-factor solution. No consensus has been reached on whether the second factor is substantively meaningful or a methodological artifact.^[125] There have been no published studies of the latent structure of GAD, and although the apparent dimensional structure of worry hints that GAD may also be dimensional, GAD is (by definition) not simply “worry” and the structure of the full syndrome will need to be evaluated directly.

Ruscio^[60] reported that GAD worriers are not the only group that experiences high worry. A substantial proportion of non-GAD worriers experience the severity of worry that is associated with a GAD sample but do not qualify for a GAD diagnosis. The DSM-IV criteria vary in how well they distinguish these two high worry groups. Criterion A (excessive worry; more days than not in past 6 months; about multiple circumstances) and Criterion E (significant distress or impairment) were the best discriminators of the groups, and further analyses of Criterion A found that “worry on more days than not in the past 6 months” was a better discriminator of GAD and non-GAD high worriers than were “excessiveness” and “worry about multiple topics.” Criterion B (difficult-to-control worry) was the least useful in distinguishing the two groups, but if excessiveness and uncontrollability of worry are thought of as individual criteria, they would have similar discriminant ability.

In a second study Ruscio^[60] examined the discrimination of the DSM-IV criteria measured as dimensional rather than categorical variables (original sample: $N = 877$, replication sample: $N = 325$). GAD worriers reported higher levels of excessiveness and uncontrollability of worry than the non-GAD high

worriers who had reported on the categorical variables that their worry was excessive or difficult-to-control. Those with GAD also reported more frequent worry and worry about minor things, frequent associated symptoms, and less distress and functional impairment than the non-GAD high worriers. Importantly, the use of dimensional measures of GAD symptoms showed that although both non-GAD and GAD high worriers experienced GAD symptoms, non-GAD high worriers experienced these symptoms less frequently and at a milder level. Ruscio concluded that the excessiveness and uncontrollability descriptors of worry may be characteristic of high worry rather than marking a clear distinction between “normal worriers” and persons with GAD, whereas the frequency and chronicity of worry and the associated impairment and distress may provide more meaningful markers of the disorder.

CONCLUSIONS

At the outset of this review, we raised the question whether the label of “generalized anxiety disorder” should be changed to “generalized worry disorder.” Alternative options include “pathological worry disorder” or “major worry disorder.” We believe that this change would recognize the importance of the defining feature of the disorder, just as the hallmark symptom of social anxiety disorder is a fear of social situations and the core component of posttraumatic stress disorder is clinically significant anxiety following a traumatic event. It has been suggested that GAD could be considered the basic anxiety disorder because worry as its defining feature reflects a basic process of anxiety.^[90,126] At the same time, current theory and research suggest that GAD is distinguished by a specific component of anxiety—worry—that is generalized to a number of future events and activities, is excessive and is negatively enforced avoidant coping strategy that is associated with symptoms of feeling restlessness, feeling keyed up or on edge, and muscle tension, and with consequent behaviors (avoidance, procrastination, reassurance) that attempt to reduce worry and/or emotional/affective distress. DSM-IV-defined GAD is an independently impairing disorder, and re-labeling the disorder to recognize its independent status could facilitate its appropriate detection and treatment.

The authors suggest that the following diagnostic-specific criteria may be appropriate for the DSM-V validity trials. The current operationalization of these associated symptoms and behaviors and their thresholds are preliminary and should be viewed as options for DSM-V. The final criteria will be informed by the DSM-V field trials.

Generalized worry disorder (generalized anxiety disorder) in DSM-V

A: The person experiences excessive anxiety and worry (apprehensive expectation):

(a) about two (or more) domains of activities or events (for example, domains like family, health, finances, and school/work difficulties)

(b) which occurs on more days than not

(c) for 3 months (or more)

B. The anxiety and worry are associated with one (or more) of the following symptoms:

(a) restlessness or feeling keyed up or on edge

(b) muscle tension

C. The anxiety and worry lead to changes in behavior shown by one (or more) of the following:

(a) marked avoidance of potentially negative events or activities

(b) marked time and effort preparing for possible negative outcomes of events or activities

(c) marked procrastination in behavior or decision-making due to worries

(d) repeatedly seeking reassurance due to worries.

FUTURE RESEARCH DIRECTIONS

This review identifies a number of unresolved issues that require answers, answers that need to be addressed through further research, and from the DSM-V validity tests and field trials:

Who should determine whether a patient's worry is excessive? Excessive means to an extreme or improper degree. Is there evidence that patients identify this threshold differently than clinicians? If so, whose judgment would result in a more valid diagnosis with respect to manifest behaviors and clinical outcomes?

Worry about minor or everyday matters is one conceptualization of excessive worry. Does including "worry about minor matters" in the diagnostic definition improve or diminish its validity?

Reducing the duration requirement to 3 months increases prevalence by an eighth to a quarter but does not change the severity, distress, or the type of person identified by the GAD diagnosis. What effect does this threshold (or briefer or longer duration thresholds) have on the reliability and validity of the diagnosis? Would the lower duration reduce discriminate validity with normal anxious reactions?

Should DSM-V retain the difficult-to-control criterion? Is this criterion largely redundant with the "excessiveness" requirement? If these are largely redundant criteria with respect to their contributions to the valid identification of cases, which one should be retained (because it improves diagnostic reliability, is more consistent with current conceptualizations of GAD, etc.)? An alternate way to operationalize "excessive" is "difficult-to-control." Would doing so in DSM-V increase the reliability and validity of the diagnosis?

We have reviewed evidence that deleting the associated symptom criterion has little effect on the prevalence of GAD. What is the value for reliability or

validity of retaining the six associated symptoms, or just the subset of these symptoms that are specific to GAD? What is the optimal threshold for criteria B and C?

Do the proposed behavioral symptoms improve the GAD diagnosis (e.g., increase differentiation from normal worry and from other anxiety and mood disorders)? If they are included in DSM-V, what number and combination of symptoms should be required for a diagnosis?

The hierarchical exclusion criteria are not included in our recommendations. Are these hierarchical criteria valid and useful for differential diagnosis?

This review for the most part, has focused on the adult literature. The paucity of data regarding disorder-specific criteria in children and adolescents necessitated this. Does DSM-IV-defined GAD and DSM-III-R OAD reflect the same pathology? Are the proposed criteria reliable and valid for the diagnosis in youth?

The authors hope that this article stimulates research that could guide these issues.

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