

Guidelines for Making Changes to DSM-V
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1. Overview:

As noted in the AJP article by Regier, et al. (2009), the categorical system established in DSM-III, -III-R, and -IV provided us with diagnostic criteria that attained acceptable levels of reliability. However, epidemiological, neurobiological, cross-cultural, and basic behavioral research conducted since DSM-IV has suggested that demonstrating construct validity for many of these strict diagnostic categories (as envisioned most notably by Robins and Guze) will remain an elusive goal. At the same time, current DSM criteria have been criticized by clinicians for not capturing the clinical complexities of many of their patients.

It is our thought that a new diagnostic paradigm must be developed that will better enable clinicians to document the clinical status of their patients and hopefully complement and stimulate further research. While DSM-V will not in itself represent a “paradigm shift,” it is intended to start a process that will lead to more useful ways of classifying and diagnosing mental disorders based on our current knowledge and reasoned predictions of where the science is heading. A part of this process for DSM-V was to examine our current knowledge regarding diagnostic boundaries. This included examinations of: i) support for current and alternative diagnostic groupings, along with an updating of Robins and Guze validators to take into account advances in research knowledge and technology; ii) comorbidity patterns and the potential role of dimensional assessments of symptoms that cross diagnostic boundaries; and iii) the role of symptom severity and disability in setting diagnostic thresholds and methods for assessing them.

At the same time, there has been no intention to abandon the categorical system that has proven useful in many ways since the publication of DSM-III. Therefore, problems evident with the current categorical diagnostic criteria sets were also examined by the DSM-V work groups and study groups with an eye toward making improvements in the system. Such problems included diagnoses with unacceptable reliability, diagnosis with allegations of “overdiagnosis,” diagnostic groups with excessive NOS diagnoses in clinical practice, and conditions with no good-fitting criterion sets. Thus, the revision process has also included consideration of changes in criteria and adding new specifiers, subtypes, and diagnoses.

At the beginning of the DSM-V revision process, four principles were laid out:

- The DSM is above all a manual to be used by clinicians, and changes made for DSM-V must be implementable in routine specialty practices.
- Recommendations should be guided by research evidence
- Continuity with previous editions should be maintained when possible (i.e., to avoid unnecessary disruption for clinicians, we should use research evidence to support maintaining the good qualities of DSM-IV, as well as to make revisions that will lead to better clinical diagnostic practice)
- Unlike in DSM-IV, there will be no *a priori* constraints on the degree of change between DSM-IV and DSM-V

The initial tasks assigned to the work groups were to:

- Determine, based on members' clinical and research knowledge, "what works and what doesn't work" for their assigned diagnoses in DSM-IV-TR
- Assess new research developments and clinical issues that have arisen since 1992
- Develop a research plan to investigate these issues, resolve problems, etc., using literature reviews and secondary data analyses

The literature review and secondary data analysis processes were intended to provide the necessary evidence to make changes in criteria, add subtypes, add new diagnoses, or delete existing diagnoses. A wide consensus of opinion supports the concept that, in general, the empirical evidence for any change introduced in DSM-V should be proportional to the magnitude of the change. That is, the larger and more significant the change, the stronger should be the required level of support. The amount of evidence needed for a change would also seem to depend on the magnitude of the problem with the existing criteria or definitions in that the more problematic the area or the diagnosis, the more compelling the rationale for change. However, differences of opinion can exist about the specific level of evidence needed for change.

Resolution of these differences is not possible since *strict operationalization of level of required studies (e.g., specifying how many studies of what sample size and quality are needed for each kind of specific change) is in our view impractical*. Our goal, we would argue, should be more modest – to try to produce broad qualitative guidelines that would provide some basic level of standardization across work groups.

2. Criteria for Change in the Current Diagnostic Classification

i. Support for Change:

A proposal for change in the current diagnostic classification should be supported by the following information:

An explication of the *reasons* for a proposed change, including the problems that prompted the examination of potential changes; a discussion of the advantages, such as a consideration of whether the change would increase the reliability or validity of the diagnosis; and whether it would lend itself to anticipated new and emerging findings in the future. A discussion of possible unintended negative effects of this proposed change, if it is made, and a consideration of arguments against making this change should also be included.

Evidence for change: A careful and thorough review of the relevant literature, and results from any secondary data analyses conducted by the appropriate work group or its advisors should be given as support for changes. Insofar as possible, the proposals for changes should be focused on single clear questions that should be conceptualized as the evaluation of two alternative hypotheses such as criteria set A is or is not superior to criteria set B or syndrome X should be a subtype of syndrome Y or an independent diagnosis. The proposal should then be organized around the individual validating criterion from the list provided. Where possible, we recommend proposals to have a

summary table listing each validator and the conclusion of the reviewers on the degree to which it supports the two alternative hypotheses.

The work group recommendations should summarize:

- The overall strength of evidence across all validators.
- Strength of evidence for each of the validators (see below).
- The magnitude of proposed changes: As noted above, a wide consensus of opinion supports the concept that the empirical evidence for any change introduced in DSM-V should be proportional to the magnitude of the change. That is, the larger and more significant the change, the stronger should be the required level of support. (Note – this section of the document does not propose criteria that should be applied to the questions of the deletion of diagnosis from DSM-IV, or the inclusion or retirement of diagnoses from the appendix. These issues are covered in sections 3 and 4 respectively. Our proposed levels of change are:
 - (1) Criteria clarification
 - (2) Modest change –
 - (a) changes to a specifier, to the examples provided in an NOS category description or to subtype criteria
 - (b) the addition of a new specifier or subtype to a diagnoses that has not been widely studied or well validated
 - (3) Substantial change –
 - (a) meaningful changes to the DSM-IV criteria for a diagnosis that has not been widely studied or well validated
 - (b) the addition of a new specifier or subtype to a well-validated diagnosis
 - (4) Major change
 - (a) meaningful changes to the DSM-IV criteria of a widely studied and well-validated diagnosis
 - (b) the addition of a new diagnosis to DSM-V

ii. Validators

The validators listed in this section can be used for at least three broad purposes:

- **Purpose 1 -- To compare the validity of two or more criteria sets**
Which set of criteria performs better against the various validators?
 Examples - would a criteria set for Anorexia Nervosa without amenorrhea be superior to the current DSM criteria for Anorexia Nervosa that includes amenorrhea?
 - Would a new set of criteria for melancholia be superior to the DSM-IV criteria for melancholia?
- **Purpose 2 -- To determine if syndrome X is closely related or relatively distinct from syndrome Y**
Given the performance of these two sets of criteria on the various validators, should the two groups of subjects defined by these two sets of criteria be

considered to have the same diagnosis, different subtypes of the same diagnosis, closely related diagnoses grouped as part of a single “family,” or quite distinct diagnoses? This can be asked at the level of individual syndromes or at a higher level about groups of syndromes.

Examples - Should grief-related depression be considered a distinct diagnosis or a form of major depression?

- Should bulimia with purging and without purging be considered subtypes of the same diagnosis or distinct diagnoses?

- Should variants of attention deficit hyperactivity diagnosis with or without impulsivity and hyperactivity be grouped together or separately?

- **Purpose 3 -- To evaluate proposed new diagnoses and/or for the retirement of diagnoses included in DSM-IV.**

Examples – Should “Night Eating Syndrome” be included as a new form of eating diagnosis in DSM-V?

Should histrionic personality diagnosis be deleted from DSM-V?

In an effort to provide a user-friendly conceptual framework for the classes of validators to be used in the DSM-V process, we modified an earlier proposal (Kendler, 1980) that organized the validators chronologically into three categories: antecedent, concurrent and predictive. Varying opinions exist about the relative importance of individual validators. While we experimented with three tiers of validators, this was seen as too complex and rigid especially given that the relative importance of the individual validators will vary across diagnoses. Nonetheless, both current informed opinion and historical precedent permit us to note (with an asterisk) those criteria which we term *high priority* and which should generally be given greatest emphasis in decisions about the overall validity of diagnosis.

I Antecedent Validators
A. *Familial aggregation and/or co-aggregation (i.e., family, twin or adoption studies)
B. Socio-Demographic and Cultural Factors
C. Environmental Risk Factors
D. Prior Psychiatric History
II Concurrent Validators
A. Cognitive, emotional, temperament, and personality correlates (unrelated to the diagnostic criteria).
B. Biological Markers, e.g., molecular genetics, neural substrates
C. Patterns of Comorbidity
[Note - while categories A and B would most typically be assessed after illness onset, they also could be assessed prior to illness onset as pre-morbid characteristics]
III Predictive Validators
A. *Diagnostic Stability
B. *Course of Illness
C. *Response to Treatment

Because of the vast differences in the size and quality of literature across areas in psychiatry, only general guidelines can be provided for the level of evidence from validators desired to support individual proposed changes. We suggest the following guidelines:

1. A broad consensus of expert clinical opinion would generally be expected for all proposed changes or additions to DSM-V.
2. In most situations, we would expect modest changes to have at least some support from the validators listed above.
3. Substantial and especially major changes should generally have broad support from several validator classes and particularly from at least one high priority validator. For most major changes, we would expect to see support from several high priority validators.
4. Substantial and especially major changes should rarely if ever be based solely on reports from a single researcher or research team.
5. Major changes should generally require consistency of support across validators. In particular, we would not generally expect to support substantial and especially major changes if a significant proportion of the literature contained evidence that contradicted the change (i.e., statistically significant results in the wrong direction).
6. Generally, for substantial and particularly major changes, at least some of the supporting literature should be of high methodologic quality.

iii. Additional considerations for evaluating proposed new diagnoses to be included in DSM-V

There are four other issues that need to be addressed in considering new categories for DSM-V. We express them here with respect to new diagnoses, but they can be easily adapted to new specifiers or new subtypes.

1. A need for the category – Here the key question is whether the proposed category identifies a distinct group of people who need appropriate clinical attention. Examples of such need would include subjects who are receiving an inaccurate diagnosis or no detection/no diagnosis in clinical settings, or who are not presenting for treatment because there is a lack of public awareness that the symptoms represent a valid entity.
2. Relationship with Other DSM-V Diagnoses - Here the key question is whether the diagnosis is sufficiently distinct from other diagnoses to warrant being considered a separate diagnosis. We would suggest the following approach. First, an expert clinical consensus is needed to address the question of whether the new diagnosis has substantial clinical overlap (e.g., common symptoms, common risk factors, response to common treatments, a common pattern of one diagnosis leading to another, strong epidemiological comorbidity) with an existing DSM-IV category. If there is a strong consensus that there is no such concern, then this issue is

settled. If there is at least modest concern, then information should be reviewed or collected with the sole goal of determining the possible degree of overlap of the new diagnosis with the existing potential “close-cousins.” If there is either strong concern or the information assessed indicates significant overlap, then a full-bore literature review should be done.

3. Potential Harm - Is there potential for harm to affected individuals or other groups of persons because of the adoption of this category in DSM-V? Could the harm that arises from the adoption of the proposed diagnosis exceed the benefit that would accrue to affected individuals? In our view, the main concern of DSM-V should be to avoid harm to the affected individuals, but sometimes broader social or forensic issues that involve potential harm to patient or non-patient groups may warrant consideration.
4. Available Treatments -- Is there evidence that, if the diagnosis was included in DSM-V, that any effective biological, psychological or social treatments for this diagnosis could potentially be found? While evidence for effective treatments should favor inclusion of a new diagnosis in DSM-V, lack of effective treatments should not necessarily weigh against inclusion as they are a number of well-accepted diagnoses in DSM-IV for which no well-demonstrated effective treatment exists.
5. Meets Criteria for a Mental (Psychiatric) Diagnosis. Finally, any proposed set of criteria for a category to be included in DSM-V should identify a mental or psychiatric diagnosis and not variations of normal psychological functioning. Dan Stein et al. have prepared a manuscript on this topic that is available to the DSM-V Task Force (See Appendix A). Their draft definition is below:

Features

- a behavioral or psychological syndrome or pattern that occurs in an individual
- the consequences of which are clinically significant distress (e.g., a painful symptom) or disability (i.e., impairment in one or more important areas of functioning)
- must not be merely an expectable and culturally sanctioned response to a particular event, for example, trance states in religious rituals .
- that reflects an underlying psychobiological disturbance
- that is not solely a result of social deviance or conflicts with society
- that has diagnostic validity using one or more sets of diagnostic validators (e.g., prognostic significance, psychobiological disruption, response to treatment)
- that has clinical utility (e.g., contributes to better conceptualization of diagnoses, or to better assessment and treatment)

Other Considerations

- no definition adequately specifies precise boundaries for the concept of either “medical diagnosis” or “mental/psychiatric diagnosis”

- diagnostic validators and clinical utility should help to differentiate a diagnosis from diagnostic nearest neighbors
- in adding/deleting entities from the nomenclature, potential benefits (e.g., provide better patient care, stimulate new research) should outweigh potential harms (e.g., hurt particular individuals, be subject to misuse)

iv. A Note about Reliability Related to Making Changes to Criteria or Adding a New Diagnosis

While this memo focuses mainly on the questions related to the use of validators in proposed changes or additions to DSM-IV decisions, two comments regarding reliability are also appropriate.

First, for purpose 1 outlined above – where the task is to evaluate two or more criteria sets for inclusion in DSM-V – the relative reliability of these two criteria should also be considered in the work group’s decision. Typically, we would hope to be able to show that for most substantial and nearly all major changes that the DSM-V proposed criteria would have at least equal reliability to the DSM-IV criteria which are being changed.

Second, for purpose 3 outlined above – where we consider new diagnoses (or subtypes) for addition to DSM-V – the demonstration of at least moderate to good reliability would also be an important criterion for their inclusion in DSM-V. In general, we would not expect to support the addition of new diagnostic entities in DSM-V without some evidence that they are reliable.

Note: the issue of reliability is also important when deleting a diagnosis or reviewing diagnoses in DSM-IV Appendix, and reliability related to these scenarios is covered in the respective sections below.

3. Criteria for Deletion of a Diagnosis

Two broad criteria should be considered in evaluating a DSM-IV category for potential deletion. The first criterion is the clinical utility of the syndrome. This judgment itself can be broken down into several components including its frequency of use, its importance in making treatment decisions, its role in stimulating the development of clinical programs and increasing attention to the diagnosis in professional and lay groups. For the assessment of clinical utility in this context, the “bottom line” question issue to be evaluated is *the magnitude of adverse effects on our patients that would arise from the deletion of the syndrome*.

The second criterion to be considered is the overall quality of information about the validity of the category. While it is unrealistic to expect all extant diagnoses in DSM-IV to meet the criteria that would be required for a new diagnosis in DSM-V (see Section 2(iii) on page 5 in this document), nonetheless, these criteria provide a helpful goal toward which we want to move with subsequent DSM editions.

In considering diagnoses for deletion during the DSM-V process, we want to focus on those diagnoses where the empirical support for their validity is minimal. This might occur because i) there are simply no or very few studies that have examined their validity, ii) there are studies but they suggest poor validity and/or produce contradictory findings or iii) there are studies but they are of very limited methodological quality. The “bottom line” question to be evaluated is *whether we have any confidence in the validity of this syndrome based on the set of validators outlined in the “Draft Guidelines” memo.*

In relation to recommended “deletion criteria,” a note about reliability is in order. In the absence of data on validity, evidence for the reliability of a DSM-IV diagnosis is not alone sufficient to justify its inclusion in DSM-V if it meets other criteria for exclusion. Evidence for low reliability, however, would contribute to evidence in favor of exclusion.

A final consideration is that attention should be paid to the “trajectory” of clinical and research interest in the diagnosis. That is, if minimal data were available on the validity of a syndrome, but there is an upsurge of interest in the condition (possibly with studies underway) so that it is plausible that in another few years this situation would change considerably, this would argue against deletion.

With this background, we propose that the prime candidates for deletion from the DSM, should be those categories which have

- i) Low clinical utility
- ii) Minimal evidence for validity.

A decision could also be made to merge a diagnosis with another diagnosis, which would have the effect of “deleting” one or more diagnoses. Research evidence (including phenomenology, genetic epidemiology, neural circuitry, etc.) may suggest that there is a false distinction between two (or more) diagnoses. In such a case, a diagnosis could be designated as a subtype or specifier of another, a new diagnosis might be created from the merged diagnoses, or the “deleted” diagnosis may simply be mentioned in the text sections for the other disorder.

4. Guidelines for Review of Diagnoses in the DSM-IV Appendix

1. Every diagnosis in the appendix needs to be reviewed by the most relevant work group during the DSM-V process, but no later than the first three months of 2010.
2. Three outcomes of this review are possible
 - a. Deletion from the appendix
 - b. “Promotion” to the main manual.
 - c. Retention in the appendix

Guidelines for this decision:

3. Deletion should be considered if
 - a. Since the last DSM iteration for DSM-IV, little or no new empirical research has been generated about the diagnosis.
 - b. Since the last DSM iteration, empirical research has been done and suggests that the diagnosis has low reliability and/or performs poorly on the validity measures specified in Section 2(ii) page 2-7 of this document.
 - c. A review of the syndrome, based on available information, leads to the judgment that the criteria listed under “Additional considerations for evaluating proposed new diagnoses to be included in DSM-V,” under Section 2(iii) on page 5 of this document, are not met. For example, it might be judged that the syndrome overlaps too strongly with an existing DSM category or there is no clinical need for the category or the syndrome does not meet the criteria for a psychiatric/mental disorder.
4. Promotion to the main manual should be considered if the diagnosis now meets the criteria for the addition of a new diagnosis to DSM-V outlined in Section 2(iii) on page 5 of this document).
5. Retention should be considered if the disorder does not clearly meet criteria for deletion or promotion. Several scenarios here are possible.
 - a. There could be some significant new empirical research has been generated about the disorder, but the evidence is judged insufficient to warrant promotion to the main manual.
 - b. There might be substantial empirical research supporting the validity of the syndrome but concerns remain about other aspects of the diagnosis that need resolution. These would include overlap with extant DSM diagnoses, possible harm associated with the adoption of the diagnosis into the main manual or a clear resolution of the clinical need for such a category.
 - c. There is a potential compelling clinical need for the category and retaining it in the appendix might facilitate the research which if sufficiently convincing could be used to promote the syndrome into a future DSM edition.

5. Summary

In summary, proposed criteria changes are made on the basis of the literature reviews and secondary data analyses that document the clinical validity of such changes. Similarly, addition of a new diagnosis or the decision to delete a diagnosis should be based on evidence and clear rationales as outlined in this document. The DSM Field Trials will provide a “first line” check on the clinical utility and feasibility of the changes (particularly changes to existing diagnostic categories and proposed new diagnoses)

along with reliability. Although some preliminary “convergent validity” may be obtained in the field test (clinicians find the criteria fit syndromes expressed by real patients), a full test of the validity of these criteria will occur after DSM-V is published. This may involve research that will test all of the validators listed above.