A Warning Sign on the Road to DSM-5: Beware of its Unintended Consequences

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We should begin with full disclosure. As head of the DSM-IV Task Force, I established strict guidelines to ensure that changes from DSM-III-R to DSM-IV would be few and well supported by empirical data. Please keep this history in mind as you read my numerous criticisms of the current DSM-V process-especially its stated ambition to effect a "paradigm shift" in psychiatric diagnosis. It is reasonable for you to wonder whether I am carrying forward an inherently conservative bias or am protecting my own DSM-IV baby. I think not and that instead I am identifying potentially grave problems in the DSM-V goals, methods, and products. It is for the reader to judge my objectivity and the accuracy of my fears that, unless its course is corrected, DSM-V will lead to many damaging unintended consequences.

Much of our work on the DSM-IV centered on spotting and avoiding possible misuses of the system. Realizing that errors in the official system of psychiatric diagnosis can lead to all sorts of dreadful problems, we established a rigorous three-stage procedure of empirical documentation to filter out mistakes. This consisted of systematic and extensive literature reviews, data reanalyses, and field testing that were conducted under well controlled conditions and in a wide variety of settings.1-3 The null position was always to keep things stable. Thus, all suggested changes had to meet a high burden of empirical proof and risk/benefit analysis.

The work on DSM-IV was transparent and widely inclusive.4 We knew how important it was to get as many critical comments as possible to assist us in spotting potential pitfalls and blind spots. To this end, we enlisted the help of over 1,000 advisors and, in particular, sought the opinions of those who were likely to be the most opposed to the possible changes being considered. In order to recruit as many comments as possible from users at large, we also prepared a regular and widely distributed newsletter and had a regular column in the journal Hospital and Community Psychiatry (now called Psychiatric Services).5

Our goal was to ensure that not only the DSM-IV Task Force, but also the entire field, would understand precisely what we were doing and how we were going about it. The methods to be used for every step in the development of DSM-IV were specified in advance and we closely adhered to them. It was made clear from the outset that there would be explicit accountability for decision-making on all changes.

We published a number of articles to establish the methodology of the DSM-IV empirical review, to indicate ways of judging the value and risks of "innovations,"5 and to fully discuss the pluses and minuses of the particular diagnostic changes that were under review.1,2,6-9

In midstream, we published a widely distributed "Options Book"10 containing the alternative criteria sets proposed for every disorder. This gave everyone a chance to join us in evaluating each decision for change in DSM-IV. After the DSM-IV was completed, we published four Sourcebooks, laying out in great detail the process and rationale for all the decisions that had been made, as well as their empirical support.11-14

Why did we go to all this trouble in preparing DSM-IV and why am I suggesting that the work on DSM-V should now undergo a sharp mid-term correction to provide safeguards by becoming far more transparent, explicit, and

conservative than it has been to date?

The work on DSM-5 has, so far, displayed an unhappy combination of soaring ambition and remarkably weak methodology. First, let's expose the absurdity of the DSM-V claim that it will constitute a "paradigm shift" in psychiatric diagnosis and indicate the dangers inherent in pursuing this false goal. The simple truth is that descriptive psychiatric diagnosis does not need and cannot support a paradigm shift. There can be no dramatic improvements in psychiatric diagnosis until we make a fundamental leap in our understanding of what causes mental disorders. The incredible recent advances in neuroscience, molecular biology, and brain imaging that have taught us so much about normal brain functioning are still not relevant to the clinical practicalities of everyday psychiatric diagnosis. The clearest evidence supporting this disappointing fact is that not even one biological test is ready for inclusion in the criteria sets for DSM-5.

So long as psychiatric diagnosis is stuck at its current descriptive level, there is little to be gained and much to be lost in frequently and arbitrarily changing the system. Descriptive diagnosis should remain fairly stable until, disorder by disorder, we gradually attain a more fundamental and explanatory understanding of causality.

Remember that there has been only one paradigm shift in psychiatric diagnosis in the last 100 years--the introduction of operational criteria sets and the multiaxial system in the DSM-III.15,16 With these methodological advances, DSM-III rescued psychiatric diagnosis from unreliability and the oblivion of irrelevancy. In the evolution of descriptive diagnosis, DSM-III-R and DSM-IV were really no more than footnotes to DSM-III and, at best, DSM-V could only hope to join them in making a modest contribution. Descriptive diagnosis is simply not equipped to carry us much further than it already has. The real paradigm shift will require an increase in our knowledge-not just a rearrangement of the furniture of the various descriptive possibilities.

Part of the exaggerated claim of a "paradigm shift" in DSM-5 is based on the suggestion that it will be introducing 30 or more dimensional ratings and that this will increase the precision of diagnosis. I am a big fan of dimensional diagnosis and wrote a paper promoting its use as early as 1982.17 Naturally, I had hoped to expand the role of dimensional diagnosis in DSM-IV, but I came to realize that busy clinicians do not have the time, training, or inclination to use dimensional ratings. Indeed, the dimensional components already built into the DSM system (i.e., severity ratings of mild, moderate, and severe for every disorder and the Axis V Global Assessment of Functioning scale) are very often ignored. Including an ad hoc, untested, and overly complex dimensional system in an official nomenclature is premature and will likely lead to similar neglect and confusion.18 Providing an opportunity for dimensional ratings certainly does not constitute a paradigm shift and should not be oversold.

If the potential gains of DSM-V are likely to be extremely modest, the potential risks are great and, so far, have gone largely unrecognized. Making changes in the diagnostic system is never cheap or free of risks. Just as when treating an individual patient, the first consideration in revising the diagnostic classification must always be to "do no harm"-and the harm inflicted by changes in the DSM diagnostic system can come in many, and usually unexpected, forms.

The most obvious adverse outcome is the significant burden to the field of having to learn and adapt to any changes included in DSM-5. This cost will be borne by all clinicians, educators, administrators, and especially by mental health researchers.19 The most noxious changes are those that frivolously lead to a need for new diagnostic instruments (or result in findings that are not comparable over studies and over time). This wastes money, slows progress, and makes it far more difficult to translate research findings into clinical practice. Any "innovations" made in DSM-5 should be clear and proven winners or they will not be worth the high overhead cost

inherent in any change. Moreover, my experience suggests that, unless strong supporting evidence is required for the changes made in DSM-5, it is likely that many of the changes will inevitably be trivial, arbitrary, and excessively influenced by the views of one or several strong-minded experts in any given work group.

There is also the serious, subtle, and ubiquitous problem of unintended consequences. As a rule of thumb, it is wise to assume that unintended consequences come often and in very varied and surprising flavors. For instance, a seemingly small and reasonable change can sometimes result in a different definition of caseness that may have a dramatic and totally unexpected impact on the reported rates of a disorder.20 Thus are false "epidemics" created. For example, although many other factors were certainly involved, the sudden increase in the diagnosis of autistic disorder, attention-deficit/hyperactivity disorder, and bipolar disorder may in part reflect changes made in the DSM-IV definitions. Note that this serious unintended consequence occurred despite the fact that careful field testing of the DSM-IV versions of two of these disorders had predicted no substantial differences in their rates as measured by DSM-III, DSM-IV, and ICD-10 criteria.21,22

The crucial lesson here is that even careful field testing is never completely accurate in predicting what will happen when the system is eventually used in the actual field. This issue becomes particularly poignant when one considers the great and skillful pressure that is likely to be applied by the pharmaceutical industry after the publication of DSM-5. It has to be assumed that they will attempt to identify every change that could conceivably lead to a marketing advantage-often in ways that will not have occurred to the DSM-5 Task Force. In order to promote drug sales, the companies may well sponsor expensive "education" campaigns focusing on the diagnostic changes that most enhance the rate of diagnosis for those disorders that will lead to the increased writing of prescriptions. It should, therefore, be no surprise if there are many new "epidemics" based on changes in DSM-V.

This risk is accentuated by the fact that the field testing for DSM-5 will receive no support from the National Institute of Mental Health. The necessary resources will not be available to measure the impact of suggested changes on the reliability and reported rates of diagnoses in the widely varied settings in which DSM-5 will be used. In addition, because no DSM-5 Options Book or first draft is being produced, the "DSM-5 field trials" are not really field trials at all-they are no more than primary data collections that will have little to say about how the final draft of DSM-5 will perform in the field. DSM-V decision-making regarding changes will therefore be flying fairly blind.

Further accentuating is that almost everyone responsible for revising the DSM-5 has spent a career working in the atypical setting of university psychiatry. This type of clinical experience is restricted to highly selected patients who are often treated in a research context. It is a basic tenet of clinical epidemiology that research results and clinical experience derived from tertiary care settings often do not generalize well when the diagnostic system has to be applied routinely in a more population-based manner.23,24

Thus, the attempt to shift paradigms in the DSM-5 is built on a shallow foundation that will greatly increase the risk of embarrassing post publication surprises. The ways to minimize the risks are to be cautious in making changes and to demand high levels of evidence about their utility and impact.

Unintended consequences are particularly unpredictable and consequential in forensic settings. Years after the DSM-IV was completed, we learned about the enormous and unintended impact of a seemingly slight wording change we had made only for technical reasons in the section on paraphilias. A misreading of our intentions in making the change had led to great confusion25-with forensic evaluators using the diagnosis of paraphilia not otherwise specified (NOS) to justify the sometimes inappropriate lifetime psychiatric commitment of rapists who

had no real mental disorder. The lesson is that even small changes can have destructive unanticipated forensic consequences.

The likelihood that DSM-5 will suffer from many and serious unintended consequences is enhanced by the way it is being done. "There are no constraints on the degree of change," according to a telling quote from Dr. David Kupfer, chairman of the DSM-V Task Force.26 The work groups have been instructed to think innovatively about the disorders under their purview. They have received little guidance on the systematic methods that can be used when conducting literature reviews.6 They have also not reviewed the DSM-IV Sourcebooks to learn from our experience in evaluating the pluses and minuses for many of the very same decisions they are now confronting. It is a fundamental error of the DSM-5 process that it has no a priori methods in place to provide standards for making changes and for instructing Work Group members on how to do a careful risk/benefit analysis of each proposal.

Even a cursory review of some of the suggestions for DSM-5 clearly illustrates the painful surprises that can inadvertently creep into a system if there are no careful doorkeepers to evaluate the risks of change. I will discuss some representative types of problems for purposes of illustration?but most of the suggested changes for DSM-V will likely have
problems of one sort or another.

Undoubtedly, the most reckless suggestion for DSM-V is that it include many new categories to capture the milder subthreshhold versions of the existing more severe official disorders. The beneficial intended purpose is to reduce the frequency of false negative missed cases?thus improving early case finding and promoting preventive treatments. Unfortunately, however, the DSM-V Task Force has failed to adequately consider the potentially disastrous unintended consequence that DSM-V may flood the world with new false positives. The reported rates of DSM-V mental disorders would skyrocket, especially since there are many more people at the boundary than those who present with the more severe and clearly "clinical" disorders. The result would be a wholesale imperial medicalization of normality that will trivialize mental disorder and lead to a deluge of unneeded medication treatments--a bonanza for the pharmaceutical industry but at a huge cost to the new false positive "patients" caught in the excessively wide DSM-V net. They will pay a high price in side effects, dollars, and stigma, not to mentions the unpredictable impact on insurability, disability, and forensics.

In my experience, experts on any given diagnosis always worry a great deal about missed cases, but rarely consider the risks of creating a large pool of false positives?especially in primary care settings. The experts' motives are pure, but their awareness of risks is often naïve. Psychiatry should not be in the business of inadvertently manufacturing mental disorders. I would therefore suggest that none of the proposed subthreshold suggestions be converted into official diagnoses of mental disorder in DSM-V. Each should instead be included in an appendix of suggested disorders that require more research and testing.

A second, related category of innovation would be to include as defined mental disorders "prodromal" forms of the schizophrenic, mood, dementing and perhaps other disorders. This again has the obvious appeal of promoting early case finding and preventive treatment, but it also has all the same devastating problems we have just discussed. For example, adding a new "pre-psychotic" category for individuals supposedly at high risk for later developing a psychotic disorder would inevitably also capture an overwhelmingly large group of false positives who would never go on to have a psychotic illness. They would nonetheless be exposed to the stigma of having a pre-psychotic diagnosis and would be overmedicated. Similarly, wouldn't it be nice to diagnose and treat early cognitive failure before it becomes dementia? But then almost everyone over sixty might qualify to receive a

probably useless, but highly promoted treatment.

This is a drug company's dream come true. They would undoubtedly find ways of penetrating the huge new markets with medications having largely unproven benefit and very substantial side effects. Also to be considered carefully are the always possible unforeseen problems caused by stigma and the unforeseen misuse of the new diagnoses in forensic, disability, and insurance settings. Finally, the clinching argument against including prodromes is that they are supported only by thin literatures and will not have extensive field trials to predict the extent of the false positive risks, especially in primary care settings. Again, it would be far better to put these suggestions in the DSM-V appendix than to make them official mental disorders.

A third category of DSM-V innovation would create a whole new series of so-called "behavioral addictions" to shopping, sex, food, videogames, the Internet, and so on. Each of these proposals has received little research attention, and they all have the potential for dangerous unintended consequences, by inappropriately medicalizing behavioral problems, reducing individual responsibility, and complicating disability, insurance, and forensic evaluations. None of these suggestions are remotely ready for prime time as officially recognized mental disorders.

I do not have space to enumerate the dangers of all the other innovative suggestions for DSM-V, but I will list just some of the riskiest that require the most careful review and caution: adult attention-deficit/hyperactivity disorder (ADHD) and adult separation anxiety disorder; making it easier to diagnose bipolar disorder; pediatric bipolar, major depressive, and trauma disorders; autism spectrum disorders; new types of paraphilias and hypersexuality disorder; and the suggested rating list to evaluate suicidality.

The DSM-V Task Force should be (but is not) routinely and quickly shooting down suggestions with obvious risks. But it should also be carefully and deeply probing into the much less obvious risks posed by every change. Getting as much outside opinion as possible is crucial to smoking out and avoiding unforeseen problems. We believed that the more eyes and minds that were engaged at all stages of DSM-IV, the fewer the errors we would make. In contrast, DSM-V has had an inexplicably closed and secretive process.27 Communication to and from the field has been highly restricted. Indeed, even the slight recent increase in openness about DSM-V was forced on to an unwilling leadership only after a series of embarrassing articles appeared in the public press.28-30 It is completely ludicrous that the DSM-V Workgroup members had to sign confidentiality agreements that prevent the kind of free discussion that brings to light otherwise hidden problems. DSM-V has also chosen to have relatively few and highly selected advisors. it appears that it will have no Options Book to allow wide scrutiny and contributions from the field.

The secretiveness of the DSM-V process is extremely puzzling. In my entire experience working on DSM-III, DSM-III-R, and DSM-IV, nothing ever came up that even remotely had to be hidden from anyone. There is everything to gain and absolutely nothing to lose from having a totally open process. Obviously, it is much better to discover problems before publication-and
this can only be done with rigorous scrutiny and the welcoming of all possible criticisms.

In summary, then, I have little confidence that the DSM-V leadership will do the kind of careful risk/benefit analysis of each proposed change that is necessary to avoid damaging unintended consequences. My concerns arise from: 1) their ambition to achieve a "paradigm shift" when there is no scientific basis for one 2) their failure to provide clear methodological guidelines on the level of empirical support required for changes; 3) their lack of openness to wide scrutiny and useful criticism; 4) their inability to spot the obvious dangers in most of their current proposals; 5) their failure to set and meet clear timelines; and 5) the likelihood that time pressure will soon lead to an

unconsidered rush of last minute decisions.

This is the first time I have felt the need to make any comments on DSM-V. Even when the early steps in the DSM-V process seemed excessively ambitious, secretive, and disorganized, I hoped that I could avoid involvement and believed that my successors deserved a clear field. My unduly optimistic assumption was that the initial problems of secrecy and lack of explicitness would self-correct and that excessive ambitions would be moderated by experience. I have decided to write this commentary now only because time is beginning to run out and I fear that DSM-V is continuing to veer badly off course?and with no prospect of spontaneous internal correction. It is my responsibility to make my worries known before it is too late to act on them. What is needed now is a profound mid-term correction toward greater openness, conservatism, and methodological rigor. I would thus suggest that the trustees of the American Psychiatric Association establish an external review committee to study the progress of the current work on DSM-V and make recommendations for its future direction.

References

1. Frances AJ, Widiger TA, Pincus HA. The development of DSM-IV. Arch Gen Psychiatry 1989;46:373-375.

2. Frances AJ, Pincus HA, Widiger TA, Davis WW, First MB. DSM-IV: Work in progress. Am J Psychiatry 1990;147:1439-1448.

3. Widiger T, Frances A., Pincus H, Davis W, First M. Toward an empirical classification for DSM-IV. J Abnorm Psychol 1991;100:280-288.

4. Widiger TA, Trull TJ. The scholarly development of DSM-IV. In: Costa e Silva JA, Nadelson CC, eds. Washington, DC: American Psychiatric Press; International Review of Psychiatry 1993; 59-78.

5. First MB, Vettorello N, Frances AJ, Pincus HA. Changes in mood, anxiety, and personality disorders. Hosp Community Psychiatry 1993;44:1034-1036, 1043.

6. Widiger TA, Frances A, Pincus HA, Davis WW. DSM-IV literature reviews: Rationale, process, and limitations. Journal of Psychopathology and Behavioral Assessment 1990;12:189-202.

7. Frances AJ, First MB, Widiger TA, Miele GM, Tilly SM, Davis WW, Pincus HA. An A to Z guide to DSM-IV conundrums. J Abnorm Psychol 1991;100:407-412.

8. Widiger TA, Frances AJ, Pincus HA, Davis WW, First MB. Toward an empirical classification for the DSM-IV. J Abnorm Psychol 1991;100:280-288.

9. Kline M, Sydnor-Greenberg N, Davis WW, Pincus HA, Frances AJ. Using field trials to evaluate proposed changes in DSM diagnostic criteria. Hosp Community Psychiatry 1993;44(7): 1621-1623.

10. Task Force on DSM-IV. DSM-IV options book: Work in progress. Washington, DC: American Psychiatric Association; 1991.

11. Widiger TA, Frances AJ, Pincus HA, First MB, Ross RR, Davis WW, eds. DSM-IV sourcebook, Volume I. Washington, DC: American Psychiatric Association; 1994.

12. Widiger TA, Frances AJ, Pincus HA, First MB, Ross RR, Davis WW, eds. DSM-IV sourcebook, Volume 2. Washington, DC: American Psychiatric Association; 1996.

13. Widiger TA, Frances AJ, Pincus HA, Ross RR, First MB, Davis WW, eds. DSM-IV sourcebook, Volume 3. Washington, DC: American Psychiatric Association; 1997.

14. Widiger TA, Frances AJ, Pincus HA, Ross RR, First MB, Davis WW, Kline, M, eds. DSM-IV sourcebook, Volume 4. Washington, DC: American Psychiatric Association; 1998.

15. Spitzer RL, Williams JBW, Skodol AE. DSM-III: The major achievements and an overview. Am J Psychiatry 1980;137:151-164.

16. Klerman GL. The significance of DSM-III in American psychiatry. In: Spitzer RL, Williams JBW, Skodol AE, eds. International perspectives on DSM-III. Washington, DC: American Psychiatric Press; 1983: 3-26.

17. Frances AJ. Categorical and dimensional systems of personality diagnosis: A comparison. Compr Psychiatry 1982;23:516-527.

18. Frances AJ. Dimensional diagnosis of personality-not whether, but when and which. Psychological Inquiry 1993;4:110-111.

19. Zimmerman M. Why are we rushing to publish DSM-IV? Arch Gen Psychiatry 1988;45:1135-1138.

20. Regier DA, Kaelber CT, Rae DS, Farmer ME, Knauper B, Kessler RC, Norquist GS. Limitations of diagnostic criteria and assessment instruments for mental disorders. Implications for research and policy. Arch Gen Psychiatry 1998;55:109-115.

21. Volkmar FR, Klin A, et al. Field trial for autistic disorder in DSM-IV." Am J Psychiatry 1994;151(9):1361-7.

22. Lahey BB. Applegate, et al. DSM-IV field trials for oppositional defiant disorder and conduct disorder in children and adolescents. In: Widiger TA, Frances AJ, Pincus HA, Ross RR, First MB, Davis WW, Kline, M, eds. DSM-IV sourcebook, Volume 4. Washington DC: American Psychiatric Association. 1998; 661-686.

23. White KL, Williams F, Greenberg BG. The ecology of medical care. N Engl J Med 1961;265: 885-892.

24. Green L. The ecology of medical care revisited. N Engl J Med 2001;443:2021-2025.

25. First M, Frances AJ. Issues for DSM-V; Unintended consequences of small changes: The case of paraphilias " Am J Psychiatry 2008;165:1240-1241.

26. Roen S. Psychiatrists rewriting the mental health bible. Los Angeles, CA: Los Angeles Times; 2009.

27. Spitzer RL. DSM-V: Open and transparent? Psychiatric News 2008;43(14): 26.

28. Carey B. Psychiatrists revise the book of human troubles. New York: New York Times; 2008.

29. Grossman R. Psychiatric manual's update needs openness, not secrecy, critics say. Chicago, Ill: Chicago Tribune; 2008.

30. Lane C. Wrangling over psychiatry's bible. Los Angeles: Los Angeles Times; 2008.