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The Missing Risk/Benefit Analyses For DSM5

By Allen Frances, MD | May 7, 2010

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DSM5 first went wrong because of excessive ambition; then stayed wrong because of its disorganized methods and its lack of caution. Its excessive and elusive ambition was to aim at a “paradigm shift.” Work groups were instructed to think creatively, that everything was on the table. Accordingly, and not surprisingly, they came up with numerous pet suggestions that had in common a wide expansion of the diagnostic system—stretching the ever elastic concept of mental disorder. Their combined suggestions would redefine tens of millions of people who previously were considered normal and hundreds of thousands who were previously considered criminal or delinquent. Then came the disorganized DSM5 method. The work groups were meant to find empirical support for their suggestions in reviews of the literature and in data reanalyses. But they were given no guidance on the methods to be used and there was no quality control or editing of their efforts. Again not surprisingly, the different work groups varied widely in the methods, thoroughness, quality, and clarity of their reviews (and the resulting rationales for the proposals offered). The anarchy was worsened by the absence of any agreed upon criteria for the threshold that had to be met before changes could be made. These were not developed until just before the first DSM5 draft was due to be posted—they should have been available as a guide and as a governor even before any work on DSM5 had begun.

Then we get to the lack of caution. However diverse in other ways, the rationales for DSM5 changes all have 2 things in common:

1. An uncritical and “cheerleading” presentation of the data and arguments that would support the proposal
2. A failure to give an adequate risk/benefit analysis of the shortcomings and dangers that might shoot it down. This fatal flaw would have been self-correcting had the work group suggestions and reviews been subjected to an open and searching interchange with the field at large. But the secrecy of the DSM5 process kept them under wraps and prevented a timely correction of the worst errors and omissions.

Each of the work group rationales provides a statement only of the benefits expected from the proposal. These have in common that “patients” presenting with a set of symptoms not currently covered by the diagnostic system will be identified—presumably so that they can be provided with a suitable treatment they would otherwise not get. Uniformly, the scientific evidence supporting each suggestion is undeveloped, weak, and unconvincing. Most remarkable though is the fact that none of these suggested new disorders has a proven effective treatment. In sum, even the “benefit” side of the equation for each of the new proposals provides little support for its inclusion.

A balanced risk/benefit assessment would then go on to present a full appraisal of the risks of each proposal, not just its presumed benefits. This has not been done for any of the proposals and must be done now. The types of risks that should be considered include;

1. What is the rate of false positive diagnosis in the studies performed to date? This will set a lower limit, since existing studies will have been performed by the most skilled diagnosticians working with a group of highly selected, relatively easy to diagnose patients.
2. Is the diagnosis likely to be made frequently in primary care practice? If so, the false positive rate will undoubtedly be much higher because the clinicians will have less time and expertise and the “patients” will be at the boundary with normal where accurate diagnosis is most difficult.
3. Are there outside forces likely to turn this proposal into a fad diagnosis that can cause a false “epidemic”? Such outside forces are numerous and extremely powerful. They have in the past included: drug companies; requirements for special school services; advocacy groups; the media; celebrity contagion (the Tiger Woods effect); and the needs of the correctional system. Although it is never possible to quantify the risk of triggering an “epidemic,” it is irresponsible not to consider this risk, especially since our field has recently experienced 4 recent fads (eg childhood bipolar, attention deficit, autism, and paraphilia NOS). There is an ever-present threat that well meaning and seemingly simple changes can have widespread unintended consequences.
4. Is there a treatment for the proposed disorder that has proven its efficacy? If not, given all the risks, what is the remaining benefit?
5. What are the risks of treatment? The way the world works, it must be assumed that the treatment will usually be a medication (whenever one is available, however unproven its benefits). What are the side effects, complications, and costs of the medication? How long will be the likely duration of treatment? What is the risk/benefit for true positives? What are the unopposed risks, costs, and complications for the false positives?
6. What are the potential forensic problems and the effects on insurance and disability?
7. What will be the impact on the new “patient’s” experience of stigma and on his sense of personal control and responsibility?
8. Will adding this diagnosis trivialize the concept of mental disorder? It was for this reason alone that we excluded caffeine dependence in DSM-IV (although it certainly sometimes exists as a clinical problem).

None of the new proposals has received anything resembling a complete “risk/benefit analysis.” To date they have received only a “benefit” analysis, which in each case has turned up no more than a modest and largely unproven upside. The deep downsides should now have the full evaluation they deserve. I am convinced that any objective balancing of the risks and benefits of these proposals would result in their being scrapped now. They are far too premature and risky to warrant field testing.

The potential negative impact of diagnostic decisions is best illustrated by the recent alarming escalation in the use of antipsychotic medication for children and teenagers. On the basis of a very poorly established indication, kids are receiving medicine that has a very well established ability to cause large and rapid weight—with consequent risks of diabetes, other medical complications, and potentially reduced life expectancy. This would seem to impose on us a very powerful and imperative “DO NO HARM” when considering the 2 most potentially dangerous of the DSM5 suggestions—“Temper Dysregulation” and “Psychosis Risk Syndrome.” But more generally, every DSM5 suggestion needs the

thorough going risk review outlined above. As a profession, we cannot walk away from the fact that our decisions, however well intended, can create enormous unexpected problems once they enter wide general usage.