

Psychiatric Times

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Two Fallacies Invalidate the DSM-5 Field Trials

By Allen Frances, MD | January 9, 2012

The designer of the DSM-5 Field Trials has just written a telling commentary in the *American Journal of Psychiatry* (AJP). She makes what I consider to be 2 basic errors that reveal the fundamental worthlessness of these Field Trials and their inability to provide any information that will be useful for DSM-5 decision making.

1. The commentary states: "A realistic goal is a kappa between 0.4 and 0.6, while a kappa between 0.2 and 0.4 would be acceptable." This is incorrect and flies in the face of all traditional standards of what is considered "acceptable" diagnostic agreement among clinicians. Clearly, the commentary is attempting to greatly lower our expectations about the levels of reliability that were achieved in the field trials-- to soften us up to the likely bad news that the DSM-5 proposals are unreliable. Unable to clear the historic bar of reasonable reliability, it appears that DSM-5 is choosing to drastically lower that bar-- what was previously seen as clearly unacceptable is now being accepted.

Kappa is a statistic that measures agreement among raters, corrected for chance agreement. Historically, kappas above 0.8 are considered good, above 0.6 fair, and under 0.6 poor. Before this AJP commentary, no one has ever felt comfortable endorsing kappas so low as 0.2-0.4. As a comparison, the personality section in DSM-III was widely derided when its kappas were around 0.5. A kappa between 0.2-0.4 comes dangerously close to no agreement. "Accepting" such low levels is a blatant fudge factor. Lowering standards in this drastic way cheapens the currency of diagnosis and defeats the whole purpose of providing diagnostic criteria.

Why does this matter? Good reliability does not guarantee validity or utility -- human beings often agree very well on things that are dead wrong. But poor reliability is a certain sign of very deep trouble. If mental health clinicians cannot agree on a diagnosis, it is essentially worthless. The low reliability of DSM-5 presaged in the AJP commentary confirms fears that its criteria sets are so ambiguously written and difficult to interpret that they will be a serious obstacle to clinical practice and research. We will be returning to the wild west of idiosyncratic diagnostic practice that was the bane of psychiatry before DSM-III.

2. The commentary also states: "one contentious issue is whether it is important that the prevalence for diagnoses based on proposed criteria for DSM-5 match the prevalence for the corresponding DSM-IV diagnoses" "to require that the prevalence remain unchanged is to require that any existing difference between true and DSM-IV prevalence be reproduced in DSM-5. Any effort to improve the sensitivity of DSM-IV criteria will result in higher prevalence rates, and any effort to improve the specificity of DSM-IV criteria will result in lower prevalence rates. Thus, there are no specific expectations about the prevalence of disorders in DSM-5."

This is also a fudge. For completely unexplained and puzzling reasons, the DSM-5 field trials failed to measure the impact of its proposals on rates of disorder. These quotes in the commentary are an attempt to justify this fatal flaw in design. The contention is that we have no way of knowing what true rates of a given diagnosis should be-- so why bother to measure what the likely impact will be on rates of the DSM-5 proposals? If rates double under DSM-5, the assumption will be that it is picking up previous false negatives with no need to worry about the risks of creating an army of new false positives.

This is irresponsible for 2 reasons. First, we are already suffering from serious diagnostic inflation. Rates of psychiatric disorder are already sky high (25% in the general population in any year; 50% lifetime) and we recently have experienced 3 runaway false epidemics of childhood disorders in the past 15 years. Second, drug company marketing has been so abusive as to warrant enormous fines and so successful as to result in widespread misuse of medication for very questionable indications. Recent CDC data suggest that the severely ill remain very undertreated, but that the mildly ill or not ill at all have become massively overtreated, especially by primary care physicians.

The DSM-5 proposals will uniformly increase rates, sometimes dramatically. Not to have measured by how much is unfathomable and irresponsible. The new diagnoses suggested for DSM-5 will (mis)label people at the very populous boundary with normality. Mixed anxiety depression and binge eating disorder will likely have astounding high rates between 5% and 10%. . . that's tens of millions people now considered "normal" suddenly converted into mentally ill by arbitrary DSM-5 fiat. Psychosis

risk and disruptive mood disorder will be extremely common in the young; minor neurocognitive among the elderly. Legions of the recently bereaved will be misdiagnosed as clinically depressed; rates of generalized anxiety and addiction will mushroom; and ADD (which has already almost tripled) will find even more room at the top. The field trial developers seem either unaware or insensitive to the unacceptable risks involved in creating large numbers of false positive, pseudo-patients.

Indeed, quite contrary to the blithe assertions put forward in the commentary, we should have rigorous expectations about prevalence changes triggered by any DSM revision. Rates should not be wildly different for the same disorder UNLESS there is clear evidence of a serious false negative problem and firm protections against creating a massive false positive problem. And new disorders with high prevalences should not be included without substantial scientific evidence and convincing proof of accuracy, reliability, and safety. We have known since they were first posted that none of the DSM-5 proposals comes remotely close to meeting a minimal standard for accuracy and safety. And now, the AJP commentary seems to be softening us up for the bad news that their reliability is also lousy.

The workers on DSM-5 ignore the often dire implications of drastically raising the prevalence of an existing disorder or adding an untested new disorder with high prevalence-- ie, the misguided and potentially harmful treatment, the unnecessary stigma, and rising health care costs that also cause a misallocation of very scarce resources. Just 2 examples. Do we really want even more antipsychotic medications prescribed for children, the elderly, and returning war veterans when these are already being used so loosely and inappropriately? Isn't the current legal and illegal overuse of stimulant medications already a big enough problem without introducing a drastically lowered set of criteria for diagnosing ADD? Sad to say, DSM-5 has failed to do an adequate risk/benefit analysis on any of its suggestions. Every one of its changes is designed to chase elusive false negatives; none protects the interests of mislabeled false positives.

Given our country's current binge of loose diagnostic and medication practice (particularly by the primary care physicians who do most of the prescribing), DSM-5 should not be in the business of casually raising rates and offering inviting new targets for aggressive drug marketing. Instead, DSM-5 should be working in the opposite direction-- taking steps to increase the precision and specificity of its diagnostic criteria. And the texts describing each disorder should contain a new section warning about the risks of overdiagnosis and ways of avoiding it. It is impossible to say what is the "right" prevalence of any disorder, but it is careless and reckless to so dramatically increase the prevalences of mental disorders without evidence of need or proof of safety.

The DSM-5 field trials have cost APA at least \$3 million (perhaps a whole lot more). They started off on the wrong foot by asking the wrong question- focusing only on reliability and completely ignoring prevalence. The deadlines for starting the trials and for delivering results have been repeatedly postponed because of poor planning, an excessively cumbersome design, and disorganized implementation. The results will be arriving at the very last minute when decisions should have already be made. And now we get a broad hint that the reliabilities, when they are finally reported, will be disastrously low.

What should be done now as DSM-5 enters its depressing endgame? There really is no rational choice except to drop the many unsupportable DSM-5 proposals and to dramatically improve the imprecise writing that plagues most of the DSM-5 criteria sets.

Scandalous Off Label Use Of Antipsychotics: Another Warning For DSM-5

By Allen Frances, MD | August 5, 2011

I never would have entered the DSM-5 controversy were it not for two of its proposals that risk furthering the already frightening overuse of antipsychotic medication, particularly in children and teenagers. DSM-5 plans to introduce two new and untested diagnoses that would offer natural targets for poor drug prescribing--psychosis risk syndrome (AKA attenuated psychotic symptoms) and temper dysregulation (AKA disruptive mood dysregulation). There is no evidence whatever that antipsychotics would confer any benefit on the kids so labeled (and too often mislabeled), but great reason to worry that this would not stop their being used needlessly and recklessly.

The DSM-5 supporters of these two proposals believe my concern is ill founded, or at least excessive. They argue that they would not recommend antipsychotics for the new diagnoses and that there is no FDA approved indication for their use. This misses the crucial point that new DSM categories, once made official, take on an independent life. If they can possibly be misused (and clearly these can), they will be misused. And experience teaches the clear lesson that antipsychotic overuse will insinuate itself insidiously and inappropriately whenever any crack of opportunity opens up.

A recent paper by Mojtabai and Olfson¹ presents a chilling testimony to the spreading creep of antipsychotic misuse. In 1996, antipsychotics were prescribed for patients with an anxiety disorder in 10% of office visits. One decade later, this had more than doubled despite there being no evidence that antipsychotics work for anxiety disorders and clear evidence that they cause dangerous side effects. Because antipsychotics have no FDA indication for anxiety disorders, all this massive overprescription was done completely off-label.

This is truly alarming, but unfortunately it is not really surprising. Antipsychotics have managed to become the top class of drugs-- generating the highest revenue with sales of \$15 billion per year-- despite the troubling facts that much of the prescribing is off label, unsupported by scientific evidence, and likely to cause the dreadful side effect of obesity with all its consequent risks. This is an astounding reflection on the lack of caution in everyday medical practice. Used appropriately, antipsychotics are extremely valuable and necessary tools-- but what could possibly justify their becoming such promiscuous best sellers?

DSM-5 cannot off-load responsibility for causing harmful unintended consequences-- especially when these are so obvious that they smack you in face. It is foolhardy to risk causing a further wave in the antipsychotic deluge. I continue to despair of a process that allows such smart and well meaning people to make such really dreadful decisions.

1. Comer JS, Mojtabai R, Olfson M. National trends in the antipsychotic treatment of psychiatric outpatients With anxiety disorders. Am J Psychiatry. 2011;Jul 28. <http://www.ncbi.nlm.nih.gov/pubmed/21799067>

DSM-5 Will Further Inflate the ADD Bubble: Child Work Group Fails to Learn From Experience

By Allen Frances, MD | July 27, 2011

Martin Whiteley is an MP who represents Perth in the Australian parliament. He has been actively involved in mental health issues and succeeded in a crusade to curb what had been Perth's alarming overdiagnosis and overmedication of Attention Deficit Disorder (ADD). Mr Whiteley has become expert in the intricacies of ADD and is alarmed that the changes suggested for DSM 5 will greatly exacerbate the ADD fad he worked so hard to tame. Read Mr Whiteley's careful item by item review and you will be alarmed, too (See: <http://speedupstill.com/dsm-5-proposal-adhd-%e2%80%93-making-lifelong-pat>).

We are already in the midst of a false epidemic of ADD. Rates in kids that were 3-5% when DSM IV was published in 1994 have now jumped to 10%. In part this came from changes in DSM IV, but most of the inflation was caused by a marketing blitz to practitioners that accompanied new on-patent drugs amplified by new regulations that also allowed direct to consumer advertising to parents and teachers. In a sensible world, DSM 5 would now offer much tighter criteria for ADD and much clearer advice on the steps needed in its differential diagnosis. This would push back, however feebly, against the skilled and well financed drug company sell. DSM 5 should work hard to improve its text, not play carelessly with the ADD criteria in a way that may unleash a whole set of dreadful unintended consequences- unneeded medication, stigma, lowered expectations, misallocation of resources, and contribution to the illegal secondary market peddling stimulants for recreation or performance enhancement.

The DSM 5 child and adolescent work group has perversely gone just the other way. It proposes to make an already far too easy diagnosis much looser.

How puzzling and troubling. Child mental health has already promoted no fewer than three false epidemics in just 15 years- ADD, childhood bipolar, and autism. Any reasonable group would now be learning from this past experience. For the future, it would be chastened, cautious, and eager to correct the damage it has done- rather than embarking on any reckless new adventures. A prudent DSM 5 would tighten its criteria for ADD and put in a black box warning against the blatant current off-the-DSM-label diagnosis of childhood bipolar. DSM 5 instead does everything wrong it possibly could with ADD and then remarkably takes the mischievous further step of adding yet another new candidate for diagnostic fad (Disruptive Mood Dysregulation Disorder) likely that will increase the already scandalous overprescription of dangerous antipsychotic medication to children. Go figure.

In many circles, the accepted wisdom is that DSM 5 workers are making such unaccountably bad decisions because they want to promote drug sales to kids. To support this accusation, cynics raise the Biederman affair and also APA's previous excessive financial support from Pharma.

This is one time when the cynics are dead wrong. The DSM 5 work group is making simply disastrous decisions for the purist of reasons. These are not people with close industry ties and their conflict of interest is intellectual, not financial. Experts in child psychiatry are dangerously naïve about the likely misuses of their well meaning suggestions. They are blind, not corrupt.

What is needed is outside supervision to curb child psychiatry's seemingly endless taste for diagnostic excess. And APA should also realize the grave harm done to its credibility by the appearance that DSM 5 is far too Pharma friendly even if this has not been the real motivation behind the bad DSM 5 proposals.

To make matters worse, the DSM 5 field trial will be completely worthless- providing no information at all about the magnitude of the rate increase in ADD that will occur once DSM 5 opens the floodgates even wider. We did careful field trials before DSM IV to compare the impact on rates of the different possible definitions and predicted a 15% increase for the one finally chosen. Instead, the rates more than doubled- courtesy of pressure from the drug companies. For obscure reasons, DSM 5 is conducting extraordinarily expensive field trials that (again perversely) avoid the only question that really counts- just how high will the rates skyrocket under the even easier to meet new DSM 5 definition.

DSM 5 will be flying completely blind into dangerous territory, unimpeded by adult supervision. The leaders of child psychiatry (who already have the unfortunate track record of producing fads) will now be given a free pass to further feed their blossoming ADD fad. Will they never learn from past mistakes?

DSM-5 Approves New Fad Diagnosis For Child Psychiatry: Antipsychotic Use Likely to Rise

By Allen Frances, MD | July 22, 2011

The DSM-5 Scientific Review Group was the last hope for an eleventh hour DSM-5 save. This hope recently died. Its first decision makes clear that the group will be no more than an easy rubber stamp willing to approve even the worst ideas dreamed up by the DSM-5 work groups. Its quick acceptance of Disruptive Mood Dysregulation Disorder (DMDD, also known as Temper Dysregulation) shows that just about anything can make it through this sham review process. Watch out for yet another fad sparked by child psychiatry.

A brief update may be in order for those of you not fully up to speed on the arcana of DSM-5 organizational functioning. The appointment of the DSM-5 scientific review group was a belated response to criticisms that many of the DSM-5 proposals did not have a reasoned rationale or deep scientific support; were reckless and radical; and would trigger diagnostic inflation and excessive use of medication.

Had it lived up to its name, the scientific review group could have ensured a safe and usable DSM-5. Initially, there was cause to be reasonably optimistic that it might serve as filter at least for the worst DSM-5 proposals. The group consisted of highly respected, experienced, and competent individuals who might be expected to hold DSM-5 to an appropriately high standard. But from its very beginning, there were also three reasons to worry that the review would be more spin than science:

1) Confidential Reporting: The review group was instructed to report confidentially only to the APA Board of Trustees. A wall of secrecy is inherently incompatible with the spirit of scientific review. All science worthy of the name should be open, transparent, and subject to the most thorough peer review from the widest of sources.

2) Independence: A scientific review group should always be independent of the science it is reviewing. How puzzling then that the Chair of the DSM-5 scientific review group had also served as a DSM-5 Task Force member and has previously staked out strong positions defending DSM-5. Interesting also that the only researcher ever to have studied DMDD also happens to sit on both the scientific review group and the child disorders work group (although she did recuse herself on the DMDD approval). The other members are less immediately involved in DSM-5, but are loyal APA soldiers, not at all independent of pressures coming from the byzantine APA political process and from its financial needs. The DSM-5 proposals should have received a completely unbiased, multidisciplinary, and truly independent review—they didn't.

3) Lack of Evidenced Based Methods: There are well developed standards for evaluating scientific evidence and applying it to medical decision making. We may never know the secret rituals that have informed the deliberations of the DSM-5 scientific review group, but we can be sure from its approval of DMDD that these had no resemblance to state of the art scientific review.

The scientific review group's first action was to issue a blank check that will allow child psychiatry to start another diagnostic fad. Child psychiatry has been on a reckless binge of overdiagnosis with no fewer than three false 'epidemics' to its credit—childhood bipolar, attention deficit, and autism. Unchastened, the field now offers up DMDD as a new and completely untested diagnosis—and amazingly enough, the scientific review group has swallowed it whole.

There is virtually no research on DMDD—it has been studied by only one group and for only six years. We don't know how high will be its rate in the bustle of primary care, its proportion of misdiagnosed false positives, its natural course and response to treatment, even its optimal definition. We can make only one safe prediction—DMDD will almost surely increase the already outrageous overdiagnosis of mental disorder in kids and the consequent overprescription of dangerous antipsychotic drugs.

Everyone (even the scientific work group and the child work group) must have known that DMDD is a made up and unstudied diagnosis with no real scientific support. The review group probably bought the child group's argument that DMDD is a lesser evil replacement for childhood bipolar disorder—less stigmatizing and less likely to result in reflex long term antipsychotic use. But their proposed fix is a disaster in the making that will most likely make an already bad situation much worse.

DMDD will capture a wildly heterogeneous and diagnostically meaningless grab bag of difficult to handle kids. Some will be temperamental and irritable, but essentially normal and just going through a developmental stage they will eventually outgrow without a stigmatizing diagnosis and a harmful treatment. Others will have conduct or oppositional problems that gain nothing by being mislabeled as mood disorder. Yet others will have serious, but not yet clearly defined psychiatric disorders that require careful and patient monitoring before an accurate diagnosis can be made.

Difficult kids suffer and cause much suffering to parents, sibs, teachers, and other kids. Everyone feels great and understandable pressure to do something. Eager clinicians and worried parents seek a label and a treatment—even in situations where it is not yet possible to make an accurate diagnosis or deliver a safe and effective treatment. Making an imprecise diagnosis and giving a risky treatment is not a reasonable solution to the troubles caused by troubled kids.

Too often prescribing a pill follows all too quickly and mindlessly after the (mis)labeling of the ill. And too often the pill is an antipsychotic with all its risks of huge weight gain and dire complications. Amazingly, the newer antipsychotics have already stretched their off label usage to become the number one revenue producing class of drugs in the United States—raking in \$15 billion per year. The inclusion of DMDD in DSM-5 will most likely add further to the overuse of antipsychotics in kids, not solve it.

It is a great puzzle that any group charged with responsibility for conducting a scientific review would take on blind faith the scientifically unsupported suggestions of the child psychiatrists—the very group who initially got us into this mess with their seemingly insatiable propensity for overdiagnosis.

So what can be done to reduce the overdiagnosis of childhood bipolar disorder? There are three steps that are much safer and more effective than adding DMDD. First, do no harm. Don't propagate new fads in a futile attempt to end old fads. Second, include a prominent black box warning in DSM-5 about the overdiagnosis of childhood bipolar disorder and its potentially dire consequences. Third, the APA and the various psychiatric, psychological, and counseling groups concerned with pediatric mental health should sponsor conferences for clinicians, parents, and teachers on the difficulties in definitively diagnosing youngsters, the need for caution, the value of accurate diagnosis, but also the risks of overdiagnosis and of overtreatment. The childhood bipolar fad needs to be attacked head on, not by adding a fake new diagnosis likely to start its own foolish fad.

The general lesson to be learned is clear—never have the fox guard the henhouse. The DSM-5 experts who are suggesting untested psychiatric diagnoses are too close to their pet proposals to be objective about them. The scientific review group is too close to the DSM-5 leadership and the APA institutional goals to provide anything resembling the needed independent review. The DSM-5 momentum towards unexpected consequences appears to be inexorable. Only mounting pressure on APA from outside groups can brake this runaway train.

Normality Is an Endangered Species: Psychiatric Fads and Overdiagnosis

By Allen Frances, MD | July 6, 2010

Fads in psychiatric diagnosis come and go and have been with us as long as there has been psychiatry. The fads meet a deeply felt need to explain, or at least to label, what would otherwise be unexplainable human suffering and deviance. In recent years the pace has picked up and false “epidemics” have come in bunches involving an ever-increasing proportion of the population. We are now in the midst of at least 3 such epidemics—of autism, attention deficit, and childhood bipolar disorder. And unless it comes to its senses, DSM5 threatens to provoke several more (hypersexuality, binge eating, mixed anxiety depression, minor neurocognitive, and others).

Fads punctuate what has become a basic background of overdiagnosis. Normality is an endangered species. The NIMH estimates that, in any given year, 25 percent of the population (that's almost 60 million people) has a diagnosable mental disorder. A prospective study found that, by age thirty-two, 50 percent of the general population had qualified for an anxiety disorder, 40 percent for depression, and 30 percent for alcohol (Drug information on alcohol) abuse or dependence. Imagine what the rates will be like by the time these people hit fifty, or sixty-five, or eighty. In this brave new world of psychiatric overdiagnosis, will anyone get through life without a mental disorder?

What accounts for the recent upsurge in diagnosis? I feel quite confident we can't blame it on our brains. Human physiology and human nature change slowly if at all. Could it be that the surge in mental disorders is caused by our stressful society? I think not. There is no particular reason to believe that life is any harder now than it has always been—more likely we are the most pampered and protected generation ever to face its inevitable challenges. It is also tempting to find environmental (eg toxins) or iatrogenic causes (eg vaccinations), but there is no credible evidence supporting either of these. There is really only one viable

environmental candidate to explain the growth of mental disorder—the widespread recreational use of psychotropic substances. But this cannot account for the extent of the “epidemics,” particularly since most have centered on children.

No. The “epidemics” in psychiatry are caused by changing diagnostic fashions—the people don’t change, the labels do. There are no objective tests in psychiatry—no X-ray, laboratory, or exam that says definitively that someone does or does not have a mental disorder. What is diagnosed as mental disorder is very sensitive to professional and social contextual forces. Rates of disorder rise easily because mental disorder has such fluid boundaries with normality.

What are the most important contextual forces?

1. DSM-III made psychiatric diagnosis interesting and accessible to the general public. More than a million copies of each edition have been sold—more to ordinary people than to mental health professionals. The widespread appeal of the DSM is in its clear definitions that allow people to diagnose themselves and family members. For the most part, this has been a useful contributor to self-knowledge and to early identification and treatment. But it can also be overdone and inevitably leads to overdiagnosis in the hands of non-clinicians.

2. This interacts with the fact that it is fairly easy to meet criteria for one or another DSM diagnosis. The definitional thresholds may be set too low and the DSM system has included many new diagnoses that are very common in the general population. The experts who establish the DSM criteria always worry more about missing cases than about casting too wide a net and capturing people who do not require a diagnosis or a treatment.

3. The pharmaceutical industry has proven to be fairly unsuccessful in developing new and improved medications. But it is wonderfully effective at marketing existing wares and is an important engine in overdiagnosis and the spread of psychiatric epidemics. The drug companies are skilled at mounting a full-court press that includes “educating” doctors, “supporting” advocacy groups and professional associations, controlling research, and direct-to-consumer advertising.

4. Patient and family advocacy groups have played an important role in calling attention to neglected needs; in lobbying for clinical, school, and research programs; and in reducing stigma and promoting group and community support. There are times, however, when advocating for those with a disorder can spill over and promote the spread of the disorder to others who are mislabeled. The mental disorders all have unclear boundaries among themselves and with normality. Clinical experience and caution are necessary in distinguishing at the boundary who does and who does not meet the criteria for the diagnosis. Well-informed self-diagnosis or family diagnosis can play a screening role and is part of being a wise consumer. But self-diagnosis is usually far too inclusive and needs trimming and validation by a cautious clinician.

5. It is no accident that the recent “epidemics” have all occurred in the childhood disorders. There are two contributing factors. The first is the push by drug companies into this new market. The second is that the provision of special educational services often requires that there be a DSM diagnosis.

6. The internet is a wonderful communication tool that provides a wealth of information and creates a social network of informed consumers. But it can also contribute to the spread of “epidemics”. Disorder-focused Web sites (often run by patients and families) provide a powerfully attractive forum and support

system that draws people who may inaccurately self-overdiagnose in order to be part of the internet community.

7. The media feeds off and feeds the public interest in mental disorders. This happens in two ways. Periodically, the media becomes obsessed with one or another celebrity whose public meltdown seems related to a real or imagined mental disorder. The mental disorder is then endlessly commented on and dissected by the media. The latest example is the Tiger Woods media frenzy which will likely lead to an “epidemic” of “sexual addiction.” Popular movies can also be contagious. Sybil helped cause a fad in multiple-personality disorder.

8. We live in a society that is perfectionistic in its expectations and intolerant of what were previously considered to be normal and expectable distress and individual difference. What was once accepted as the aches and pains of everyday life is now frequently labeled a mental disorder and treated with a pill. Eccentrics who would have been accepted on their own terms are now labeled as sick (with Asperger's) and in need of therapeutic intervention. Mental disorder labels can provide cover for societal problems. Criminal behavior has been medicalized (eg, rape as a psychiatric disorder) because prison sentences are too short and such labeling allows for indefinite psychiatric commitment.

All the above factors interact to produce follow-the-leader diagnostic fads that punctuate a general pattern of overdiagnosis. The definition of fad is “a temporary fashion, notion, manner of conduct especially one followed enthusiastically by a group.” What makes something a psychiatric fad is that a psychiatric label seems to explain some common, nonspecific, problematic symptom or behavior, and that label is suddenly given to everyone. The fact that everyone is doing it reduces the stigma of the diagnosis and leads to more people getting the diagnosis. Then, like the old adage that if you have a hammer, everything looks like a nail, the new label gets twisted to fit cases which really don't fit it simply because the label itself is popular and accepted.

There is no objective way to determine what should be the proper rate of mental disorder in the general population. My view is that DSM-IV is almost certainly overinclusive, but I would not recommend tightening the criteria until we have clear evidence this would do more good than harm. The DSM-5 bias to thrust open the diagnostic floodgates is supported only by flimsy evidence that does not come close to warranting its great risks of harmful unintended consequences. It is too bad that there is no advocacy group for normality that could effectively push back against all the forces aligned to expand the reach of mental disorders.

Opening Pandora's Box: The 19 Worst Suggestions For DSM5

By Allen Frances, MD | February 11, 2010

I have previously criticized the DSM5 process—for its unnecessary secretiveness, its risky ambitions, its disorganized methods, and its unrealistic deadlines.¹⁻⁶ Now, it is finally time to evaluate the first draft of the recently posted DSM5 product (at www.DSM5.org).

Poor and inconsistent writing

Perhaps it should occasion no surprise that a flawed process should yield a flawed product. The most fundamental problem is the poor and inconsistent writing. Admittedly, early Work Group drafts are often written imprecisely and with varying quality, but it is surprising that the DSM5 leadership has failed to edit for clarity and consistency. It would be a waste of effort, time, and money to conduct field trials before the new criteria sets receive extensive revision. The poor writing is also a bad prognostic sign,

suggesting that the DSM5 text sections for the various disorders may eventually be equally inconsistent, variable in quality, and sometimes incoherent.

Higher rates of mental disorder

In terms of content, most concerning are the many suggestions for DSM5 that would dramatically raise the rates of mental disorder. These come in 2 forms:

1. New diagnoses that would be extremely common in the general population (especially after marketing by an ever alert pharmaceutical industry)
2. Lowered diagnostic thresholds for many of the existing disorders.

DSM5 would create tens of millions of newly misidentified false positive “patients,” thus greatly exacerbating the problems caused already by an overly inclusive DSM4.⁷ There would be massive overtreatment with medications that are unnecessary, expensive, and often quite harmful. DSM5 appears to be promoting what we have most feared—the inclusion of many normal variants under the rubric of mental illness, with the result that the core concept of “mental disorder” is greatly undermined.

Unforeseen consequences

A third pervasive weakness in the DSM5 options is their insensitivity to possible misuse in forensic settings. Work Group members cannot be expected to anticipate the many ways lawyers will try to twist their good intentions, but it is incumbent on the DSM5 leadership to establish a thorough ongoing forensic review that would identify the many likely instances of proposals with important forensic implications (for example, the expansion of pedophilia to include attraction to adolescents).

Space constraints (as well as my own blind spots and limitations in expertise) make this a limited survey, both in the numbers of issues discussed and the depth of discussion possible on each. I would encourage the field to identify the additional problems that will require correction.

PROBLEMATIC NEW DIAGNOSES

The **Psychosis Risk Syndrome** is certainly the most worrisome of all the suggestions made for DSM5. The false positive rate would be alarming—70% to 75% in the most careful studies and likely to be much higher once the diagnosis is official, in general use, and becomes a target for drug companies.⁸ Hundreds of thousands of teenagers and young adults (especially, it turns out, those on Medicaid) would receive the unnecessary prescription of atypical antipsychotic drugs.⁹ There is no proof that the atypical antipsychotics prevent psychotic episodes, but they do most certainly cause large and rapid weight gains (see the recent FDA warning) and are associated with reduced life expectancy—to say nothing about their high cost, other side effects, and stigma.

This suggestion could lead to a public health catastrophe and no field trial could possibly justify its inclusion as an official diagnosis. The attempt at early identification and treatment of at risk individuals is well meaning, but dangerously premature. We must wait until there is a specific diagnostic test and a safe treatment.

Mixed Anxiety Depressive Disorder taps nonspecific symptoms that are widely distributed in the general population and would therefore immediately become one of the most common of all the mental disorders in DSM5. Naturally, its rapid rise to epidemic proportions would be ably assisted by pharmaceutical marketing. It is likely that medication would not be much more effective than placebo because of the high placebo response rates in milder disorders.¹⁰

Minor Neurocognitive Disorder is defined by nonspecific symptoms of reduced cognitive performance that are very common (perhaps almost ubiquitous) in people over fifty. To protect against false positives, there is a criterion that requires objective cognitive assessment to confirm that the individual has decreased

cognitive performance, but getting a meaningful reference point is impossible in most instances and the threshold has been set to include a whopping 13.5% of the population (ie, the percent of population within the first and second standard deviation). Moreover, the suggestion for objective testing will probably be widely ignored in the primary care settings where the bulk of diagnosing will be done.

Medicalizing the expectable cognitive impairments of aging will result in much unnecessary treatment with ineffective prescription drugs and quack folk remedies. These will undoubtedly attain great popularity since there will likely be a very high placebo response rate.

Binge Eating Disorder will have a rate in the general population (estimated at 6%) and this will probably become much higher when the diagnosis becomes popular and is made in primary care settings. The tens of millions of people who binge eat once a week for 3 months would suddenly have a “mental disorder”—subjecting them to stigma and medications with unproven efficacy.

Temper Dysfunctional Disorder with Dysphoria is one of the most dangerous and poorly conceived suggestions for DSM5—a misguided medicalization of temper outbursts. The “diagnosis” would be very common at every age in the general population and would promote a large expansion in the use of antipsychotic medications, with all of the serious attendant risks described above. Apparently, the Work Group was trying to correct excessive diagnosis of childhood bipolar disorder—but its suggestion is so poorly written that it could not possibly accomplish this goal and instead would it would create a new monster.

The misapplication of this diagnosis would provide a blanket excuse for reduced personal responsibility and will lead to forensic nightmares. It is a nonstarter.

Paraphilic Coercive Disorder would expand the pool of sex offenders who are eligible for indefinite civil commitment because they have a “mental disorder” to include cases of sexual coercion. Paraphilic Coercive Disorder was initially considered for inclusion in DSM-III-R (under the name Paraphilic Rapism) but was rejected because it was impossible to reliably and validly differentiate those rapists whose actions are the result of a paraphilia from the large majority of rapists who are motivated by other factors (such as power). Given the facts (acknowledged in the rationale section) that most rapists are savvy enough to deny sexual fantasies and the unreliability (and unavailability) of laboratory testing, the diagnosis will inevitably be based only on the person’s behavior, leading to a potentially alarming rate of false positives with consequent wrongful indefinite commitment.¹¹

Hypersexuality Disorder would be a gift to false positive excuse seekers and potential forensic disaster. Another clear nonstarter.

A **Behavioral Addictions** category would be included with the substance addictions section and would start life with one disorder, Pathological Gambling (transferred from Impulse Disorders section). Next in line might be a new category for Internet Addiction. This could provide a slippery slope leading to the back door inclusion of a variety of silly and potentially harmful diagnoses (ie, “addictions” to shopping, sex, work, credit card debt, videogames etc, etc, etc) under the broad rubric of “behavioral addictions not otherwise specified.” The construct “Behavioral Addictions” represents a medicalization of life choices, provides a ready excuse for off loading personal responsibility, and would likely be misused in forensic settings.

LOWERED THRESHOLDS

The greatest general impact would come from the suggestion to eliminate the “clinical significance” criterion required in DSM4 for each disorder that has a fuzzy boundary with normality (about two-thirds of them). These were included to ensure the presence of clinically significant distress or impairment when the symptoms of the disorder in mild form might be compatible with normality. Removing this

requirement would reduce the role of clinical judgment as a gatekeeper in determining the presence or absence of mental disorders and thus would increase the already swollen rates of psychiatric diagnosis.

Attention Deficit/Hyperactivity Disorder. The DSM4 wording changes (along with extremely active drug company marketing) contributed to escalating rates of ADD - accompanied by the widespread misuse of stimulant medications for performance enhancement and the emergence of a large secondary illegal market.¹² There are 4 suggestions for DSM5 that would make this existing overdiagnosis much worse.

- The first change is to raise the required age of onset from 7 to 12.¹³
- The second is to allow the diagnosis based only on the presence of symptoms, not requiring impairment.
- The third is to reduce by half the number of symptoms required for adults.

These 3 changes greatly reduce the specificity of the ADD diagnosis in adolescents and adults and will result in a further flood of false positives and of resulting stimulant misuse for performance enhancement.¹⁴

- The fourth change is to allow the diagnosis of ADD in the presence of autism. This might create the interaction of 2 false epidemics, encouraging increased stimulant use in an especially vulnerable population.

Addiction Disorder. DSM5 proposes to eliminate the distinction between substance abuse and substance dependence, lowering the threshold for diagnosing the new unified category— “addiction”—that would be introduced to replace them both. This confounding of episodic binge use with continuous compulsive use loses valuable clinical information about their very different treatment and prognostic implications. It also seems unnecessarily stigmatizing and misleading to label with the loaded word addiction those whose problem is restricted to intermittent substance use.

Autism Spectrum Disorder. Asperger’s disorder would be collapsed into this new unified category. Although this consolidation appeals to some experts, it remains controversial and presents serious problems. Those with Asperger’s (which is much less impairing) will be stigmatized by the association with classic autistic disorder. Moreover, in the average everyday practice conducted by non-experts, the spectrum concept will likely further fuel the “epidemic” of loosely defined autism that was already been triggered by the introduction of Asperger’s in DSM4.¹⁵

Medicalizing Normal Grief. DSM5 would reverse 30 years of diagnostic practice and allow the diagnosis of Major Depression to be made for individuals whose grief reaction symptomatically resembles a Major Depressive episode (eg, 2 weeks of depressed mood, loss of interest in activities, insomnia, loss of appetite, and trouble concentrating immediately following the loss of a spouse would be a mental disorder. This is radical and astounding change that may be helpful for some individuals, but will cause a huge false positive problem—especially since there is so much individual and cultural variability in bereavement. Of course, grief would become an extremely inviting target for the drug companies.

Pedohebephilia is one of the most poorly written and unworkable of the suggested criteria sets. Expanding the definition of pedophilia to include pubescent teenagers would medicalize criminal behavior and further the previously described misuse of psychiatry by the legal system. Certainly, sex with under-age victims should be discouraged as an important matter of public policy, but this should be accomplished by legal statute and appropriate sentencing, not by mental disorder fiat.

Deleting the Multiaxial System. This would result in the loss of much valuable clinical information. Multi-axial diagnosis provides a disciplined approach to distinguishing between state and trait (Axis I versus Axis II) and to determining the contributions of medical conditions (Axis I II) and of stressors (Axis IV) to the diagnosis and treatment of psychiatric disorders. The GAF score (Axis V) provides the most convenient and familiar rating of overall functioning. No compelling rationale is offered for making

so radical a change.

Various Small Changes. There are numerous small editorial changes meant to help clarify the existing criteria sets. Some of these appear to be improvements, many are trivial, and some are worse than their DSM4 counterparts. Any possible gain from wording changes has to be weighed against the risks that the new version will create its own set of unanticipated consequences. The old, tried and true criteria sets have withstood the test of time -in some instances for 30 years-without creating forensic problems. Moreover, even small changes can have a dramatic impact on the definition of caseness and resulting rates of disorder¹⁶ needlessly compromising the interpretation of all the clinical and epidemiological research that was done before versus that done after DSM5.

Dimensional Assessments

Three dimensional assessments (for severity, co-morbid symptoms, and personality traits) are suggested for DSM5. Dimensions are most appropriate in describing continuously distributed phenomena that can be reduced to numbers. It has been widely accepted for several decades that adding dimensions would help to solve the categorical system's problem with fuzzy boundaries- thus improving the accuracy and precision of psychiatric diagnosis.¹⁷ Unfortunately, however, the field has never achieved consensus on which dimensions to choose and how best to measure them. Moreover, and most crucial, clinicians find dimensional ratings far too unfamiliar and cumbersome for use in everyday practice and all efforts to include even a few simple dimensional ratings into previous DSM's have been met by clinician resistance and neglect. The DSM5 dimensional proposals are especially problematic—ad hoc, unworkably complex, vague, untested, and premature. If anything, the poorly executed introduction of unwieldy dimensions into DSM5 is likely to give them a bad name and poison the well for their future necessary acceptance. It is also possible that the use of dimensions may create problematic unintended consequences in insurance, disability, and forensic determinations. The possible introduction of dimensions by DSM5 has been greatly oversold as a “paradigm shift.” With a few exceptions, it would probably be advisable to include the suggested dimensional ratings in the DSM5 appendix or in a separate volume for diagnostic instruments.

Severity ratings tailored for each disorder. In fact, this approach was tried for 8 categories in DSM3R, but was dropped in DSM4 because the anchors of the severity ratings were not validated and the system was too cumbersome for routine clinical use. The severity ratings suggested for DSM5 are bewilderingly inconsistent across sections in their format and quality and are largely ad hoc, extremely complicated and totally impractical for use in clinical settings.

Ratings on “crosscutting” symptoms that exist across a number of different diagnoses to supplement the primary categorical diagnosis. Such assessment might be useful in some settings, but is far too cumbersome for use in routine clinical practice.

Dimensional ratings for personality. These would, in theory, have clear advantages over the clumsy categorical approach to personality assessment. In practice, however, the multiple, complicated, confusing, and cumbersome systems suggested for DSM5 would be far too unfamiliar and time consuming to ever be used by clinicians. Another side effect would be deletion of five of the personality disorders (paranoid, narcissistic, histrionic, dependent, schizoid) from the manual.

CONCLUSIONS

It will likely be argued by the DSM5 leadership that I am unduly and prematurely alarmist, that they are still early in the DSM5 process, and that any problematic suggestions will eventually be weeded out in the field trials. This is putting the cart (ie field testing) before the horse (ie having usable criteria sets to test) and continues to miss the point that DSM5 has been and remains in serious trouble. I feel it is my responsibility to raise clear alarms now because the past performance of the DSM5 leadership does not inspire confidence in its future ability to avoid serious mistakes.

What leads me to this pessimistic conclusion? Every step in the development of DSM5 has been secretive

and disorganized. The leadership has established a consistent track record of proposing unrealistic plans and impossible to meet timetables—with predictably erratic course changes and repeatedly missed deadlines. It was, for example, announced last May at the APA annual meeting (and in the press) that the DSM5 field trials were about to begin in the summer of 2009. Then, it turned out that none of the necessary preparatory steps had been accomplished and the field trials had to be postponed for at least a year. During the past 6 months, there have been several successive target dates for posting the DSM5 drafts—each of which passed unmet causing unexplained postponements. Poor planning and execution have already forced a 1 year delay in the projected DSM5 publication date (to May 2013).

The DSM5 process is already nearly 3 years old. By now, a careful editing process should have resulted in refined proposals that were all plausible and all clearly and consistently written. Field trials are arduous and expensive and make sense only for testing the precise wording of criteria sets that have a real chance of making it into the manual—not for the many poorly written and far out suggestions that have just been posted. It seems prudent to identify and root out problems now lest they sneak through in what will likely be an eventual mad rush to complete DSM5. My fear remains that left to its own devices and without continued external pressure and assistance, the DSM5 process may never produce a quality product (even with the extended deadline of 2013).

There is, however, one criticism of the DSM5 process that demands a clear rebuttal. It has been alleged that those working on DSM5 have financial and/or professional conflicts of interest which bias them to make decisions that increase the rates of psychiatric diagnoses (ie, to benefit drug companies, or to increase research funding, or to expand the practice opportunities of mental health workers. I know most of the people working on DSM5 and can assure you that this accusation is simply false. They have the highest integrity and are making (what I believe to be often mistaken and sometimes even dangerous) suggestions because they sincerely, but naively, believe that this is where the science is leading them—not for any personal or professional gain.

How can such smart and scrupulous people make so many bad suggestions? It has been my consistent experience (gained working on the previous three DSM's) that each Work Group always has a strong (and seemingly irresistible) bias for expanding the boundaries of the disorders in its section. This expectable Work Group diagnostic imperialism must always be recognized and resisted. Experts understandably place a high value on reducing false negatives for their favorite disorders and in avoiding the need to resort to the label “not otherwise specified.” They hope in this way to identify patients early in their course and to institute treatments that will be effective in reducing the lifetime burden of illness.

Unfortunately, Work Group members usually have a correspondingly huge blind spot—missing the fact that every effort to reduce the rate of false negatives must inevitably raise the rate of false positives (often dramatically and with dire consequences). It is inherently difficult for experts, with their highly selected research and clinical experiences, to appreciate fully just how poorly their research findings may generalize to everyday practice—especially as it is conducted by harried primary care clinicians in an environment heavily influenced by drug company marketing. They also consistently underestimate the costs and risks of medication treatment when it is given to those who don't really need it. If we are ever to realize the wished for gains of early case finding, we must first have both specific diagnostic tests and safe and effective treatments. In contrast, the DSM5 suggestions display the peculiarly dangerous combination of nonspecific and inaccurate diagnosis leading to unproven and potentially quite harmful treatments.

I wish to emphasize that the problems in this DSM5 draft are not at all the fault of the Work Group members who have labored hard under very unpromising conditions. The DSM5 options are poorly conceived and executed because of the interaction of 4 unfortunate decisions made by the DSM5 leadership:

1. Requiring unnecessary confidentiality agreements that insulated the Work Groups from the usual and necessary corrective interaction with the field

2. Tightly restricting Advisors to a small and highly selected group
3. Establishing the expectation that Work Groups be innovative rather than risk/benefit conscious
4. Providing the Work Groups with remarkably little guidance, consistency, and editorial assistance.

Because of the secretive and closed nature of the DSM5 process, the expectable enthusiasms of the experts who comprise the Work Groups have not been balanced, as they must always be, with real world practical clinical wisdom and a careful risk/benefit analysis of the possible unintended consequences of every suggestion.

It would be reckless now to rely on the complacent assumption that all these problems will eventually come out in the wash. By its previous actions and inactions, the DSM5 leadership has sacrificed any “benefit of the doubt” faith that their process will be self-correcting in a way that guarantees the eventual elimination all of the harmful options.

There is, however, some cause for measured optimism regarding the future of the DSM5 process based on the fact that it does respond, albeit reluctantly, to external pressure. There have been significant and encouraging improvements during the past several months. A DSM5 Oversight Committee was finally appointed and has played a very beneficial role in correcting the most egregious problems in the previous methods and deadlines. The ill conceived plan to conduct field trials before having a public review of criteria was dropped and the unrealistic field trial and publication deadlines were each extended by a year. The additional time provided by the extended deadlines, if used well, would be sufficient to produce a serviceable DSM5.

What needs to be done next? The responsibility (and opportunity) for rescuing DSM5 falls most heavily on the field at large and on the Oversight Committee. Now that the DSM5 drafts are finally open for wide review, it behooves the field to be active in identifying problems and providing the needed pressure to ensure they will be corrected. My recommendations for the Oversight Committee are:

1. Extend the period allotted for public review to 3 months.
2. Use this time to ensure the careful editing of each word of each item of every criteria set to provide the clarity and consistency that is now sorely lacking and is absolutely necessary before any meaningful field testing can begin.
3. Post field trial methods for public review.
4. Appoint 3 subcommittees reporting to the Oversight Committee (responsible, respectively, for monitoring forensic review, risk benefit analysis, and field trials.
5. Post the literature reviews and plans for ICD-11 harmonization.

Every future step in the preparation of DSM5 should involve active interaction with the field and with the Oversight Committee and its subcommittees. Unnecessary secrecy has caused the current problems and only full transparency and openness to outside input will solve them.

I have had the space and expertise to identify only the DSM5 trouble spots that are most obvious to me. The rest is up to you. Please take the time to review the DSM5 options (at least in your areas of interest) and supply your input. They can be found at www.dsm5.org.

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