

Response of the DSM-V Sexual Dysfunctions Subworkgroup to Commentaries Published in JSM

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We would like to extend our thanks to Irwin Goldstein for suggesting a presentation on the Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-V) at the International Society for the Study of Women's Sexual Health (ISSWSH) 2010 Annual Meeting and for soliciting commentaries from well-respected clinicians and investigators in *The Journal of Sexual Medicine*. Our goal in publishing our literature reviews and initial proposals for revision of the Diagnostic and Statistical Manual of Mental Disorders, 4th edition, text revision (DSM-IV-TR) classification of sexual dysfunctions was to elicit feedback from a multidisciplinary, multinational group such as the readers of this journal.

First, let us briefly review the DSM-V process. The subworkgroup on the Sexual Dysfunctions (chaired by Taylor Segraves), part of the DSM-V Sexual and Gender Identity Disorders Workgroup (chaired by Kenneth J. Zucker), was formed in late 2007. Our first task was to review the empirical evidence concerning DSM-IV-TR diagnostic criteria and to ascertain if there was sufficient evidence to propose any alterations for DSM-V.

Initially, we appointed a group of international experts (known as DSM-V advisors) to assist in our deliberations. This was followed by extensive literature reviews and our initial proposals, which were modified following feedback from advisors and from commentaries in *JSM*. The reviews on male sexual disorders were published in *JSM* and those on female sexual disorders in the *Archives of Sexual Behavior*. Over the past year, we have presented these proposals at a number of professional meetings, and our workgroup has had biweekly conference calls, at least twice yearly face-to-face meetings, and countless e-mail exchanges. This

has led to the recent proposals which have been published on the DSM-V website. It is important to realize that the proposals for diagnostic criteria are a work in progress. The final DSM-V is slated to be published in May 2013 following a year of field testing of proposed criteria.

We will now respond, first to the commentaries on male sexual disorders and then to those on female sexual disorders. Since it would be impractical to address every issue raised by the commentaries, we will focus on the major concerns raised.

Reply to Commentaries on Male Sexual Disorders

We found the commentaries on male orgasmic disorder helpful and will modify the provisional criteria accordingly. Several authors commented that although ejaculation and the experience of orgasm usually occur together, they are mediated by different mechanisms, and therefore, a merged diagnosis might not adequately address conditions in which one is impaired and the other is not. In response to this, we included a statement that the clinician should also record alterations in subjective sensation when coding delayed ejaculation. One commentator indicated that we should include a separate code for retrograde ejaculation. To our knowledge, most of the evidence concerning retrograde ejaculation indicates that it is a drug side effect or the product of a general medical condition (e.g., diabetes mellitus); these cases should therefore be coded as a Sexual Dysfunction Due to a General Medical Condition. If the cause is unknown or suspected to be psychiatric in etiology, one could code the problem as a Sexual Disorder Not Otherwise Specified (Not Elsewhere

Classified in DSM-V). The presumed infrequent occurrence of retrograde ejaculation of psychological etiology is too low to justify it as a separate diagnostic category.

Several commentators objected to the proposed change of the name of Premature Ejaculation to Rapid Ejaculation. It was correctly pointed out that we have no evidence that the process of ejaculation is rapid. Others objected to modifying an existing well-recognized term such as Premature Ejaculation in any manner. In response, we have recommended that the name of the disorder be changed to Early Ejaculation. "Premature" has an unnecessarily pejorative connotation similar to the word "impotence." It should be noted that impotence was a commonly used term that was successfully modified to erectile dysfunction (ED).

A number of individuals objected to defining early ejaculation as ejaculation occurring within approximately 1 minute of initiating sexual activity. This definition, similar to the one adopted by the International Society of Sexual Medicine [1–3], is based on substantial research. Others commented that we should include a statement regarding absence of a sense of control over ejaculation. Our proposed criteria require that ejaculation occur before an individual wishes it, which would appear to address the issue of lack of control.

Regarding the proposed diagnostic criteria for ED, most commentators objected to the duration and severity criteria (i.e., 6-month duration of symptoms, on 75% or more of sexual events). It was argued that the 75% criterion was arbitrary. In fact, this threshold was based on a number of epidemiological studies, where the prevalence of sexual problems occurring almost all of the time was much lower than the prevalence of disorders occurring less frequently. In the Global Study of Sexual Attitudes and Behaviors [4,5], the overall prevalence of self-reported erectile problems was 18.8% in non-European Western respondents. However, only 3.5% of men reported frequent erectile difficulties, whereas 8.5% and 6.6% reported this to be an occasional or periodic problem, respectively. Since there is evidence that ED may be a self-limiting disease [6], we elected to restrict the diagnosis to problems occurring frequently or almost always. We arbitrarily defined frequent and almost always as 75%. A number of 80% or 90% could have been chosen with similar justification. Some commentators objected to the 6-month duration criterion, stating that it was based on only one cross-sectional study [7]. This

criticism is accurate in that this is the only study to use a 6-month criterion. However, other studies [8,9] have found evidence of remission of ED prior to the advent of phosphodiesterase type 5 (PDE5) inhibitors. A follow-up study of men diagnosed with ED in the Massachusetts Male Aging Study found that 40% of men diagnosed with ED reported remission 9 years later. The majority of those reporting remission of symptoms of ED reported total remission of symptoms.

One commentator suggested that the majority of men with ED have underlying vascular disease and implied therefore that ED does not belong in the DSM-V; however, no evidence was provided for this statement. We would point out that the observation that a treatment reverses a medical condition does not establish etiology. For example, we have no evidence that bipolar disorder is the result of a lithium deficiency. Similarly, over-the-counter antihistamines are used to treat insomnia and we have no reason to believe that insomnia is the result of histamine excess. This is not to dispute that endothelial disease is implicated in many cases of ED. But there is also clear evidence of psychiatric conditions associated with ED. For example, studies have indicated a high frequency of ED in men with post-traumatic stress disorder, obsessive compulsive disorder, major depressive disorder, and panic disorder [6].

Finally, one author suggested that the 6-month duration criterion required for an ED diagnosis might contribute to some men having treatment delayed. Although the PDE-5 inhibitors have a good safety profile, they are not without side effects, and should not be prescribed for conditions which might remit without intervention. It is also important to remember that we have little data on the adverse effects of inappropriate use of PDE-5 inhibitors. One study found that recreational use of ED medications was associated with less confidence in erectile functioning and might lead to psychological dependence on such medication [10].

Reply to Commentaries on Female Sexual Disorders

We appreciated the many constructive comments on our proposals for diagnostic criteria for female sexual disorders. Despite these constructive comments, we were dismayed by the tone and content of some of the commentaries. For example, one comment that "... the reformers seem animated by the holy fire of reducing the space of industry, a

behavior dramatically remote from science and from the interests of patients” was puzzling, as our diagnostic proposals are not linked to treatment recommendations.

In replying to some of the points raised in the invited commentaries, we would first like to take the opportunity to address some apparent misconceptions that were raised in the Introduction section as well as referenced by some of the commentaries. There appears to be a belief that members of the DSM-V subworkgroup do not view the proposed changes as controversial. We are not clear where this perception comes from. As a committee, we are very aware that some of the changes we are proposing, including those for sexual interest/arousal disorder, involve major revision of DSM-IV-TR categories. In fact, we were asked by the American Psychiatric Association to rate the “magnitude” of the changes we proposed; for all of the female sexual disorders, we rated the proposed changes as major (4 on a 1–4 point scale). A second misconception is that our subworkgroup may be prioritizing psychological etiologies over organic/medical etiologies, as reflected in the statement that the invited commentaries show “beyond a reasonable doubt that problems of female sexual dysfunction are not purely psychological and therefore need to be considered from the biopsychosocial perspective.” We would certainly agree that sexual problems in women need to be considered from a biopsychosocial perspective and are somewhat puzzled by this comment. Our subworkgroup feels strongly that our proposed criteria reflect a greater appreciation of the biopsychosocial perspective than the DSM-IV classification of female sexual disorders.

We appreciated the very thoughtful and provocative commentary by DeRogatis, as it gives our subworkgroup an opportunity to justify some of the proposed changes. There are many statements made in this commentary that suggest dire consequences if our proposed criteria are adopted (e.g., “I believe their endorsement would have a seriously regressive effect on clinical practice, research and the development of knowledge . . . quite possibly for the next decade or more”). However, we could not discern any recommendations in this commentary for what changes *should* be made, nor any acknowledgement that the DSM-IV-TR criteria for female desire and arousal disorders were problematic (for a detailed discussion of previous critiques of the DSM-IV-TR classification of female sexual dysfunctions, see [11] and [12]). There was then an interesting discussion on the

differential risks of “lumping vs. splitting.” We believe that DeRogatis may be misinterpreting our proposals. All of the symptoms we have listed in our proposed diagnostic criteria can be differentiated and studied separately, in research studies as well as in the clinical situation. We fail to understand what the dangers of merging these two disorders are, particularly for clinical practice, where we believe that our proposed criteria reflect clinical reality much better than DSM-IV-TR criteria. For example, a very common presentation is the woman who complains of lack of interest, reduced sexual excitement, and lack of awareness of any signs of physical arousal. Complaints of inadequate lubrication, on the other hand, as the sole or even the primary symptom, present relatively infrequently, except in some specific gynecologic conditions. In the research context, validated measures of women’s sexual functioning (e.g., the Female Sexual Function Index; FSFI) separately measure symptoms of desire and arousal; thus, even with the proposed Sexual Interest/Arousal Disorder, these different symptoms could be assessed separately and differential response to treatment ascertained. There is a significant body of literature supporting the high degree of overlap between desire and subjective arousal concerns that, we believe, justify the merging of these symptoms into one syndrome. DeRogatis used the example of why depression and anxiety would not be merged although they share symptoms. In fact, in DSM-V, there is a proposal for “Mixed Anxiety Depression” in recognition of the fact that there is a distinct syndrome in which both depressive and anxious symptoms are present; the rationale here parallels our justification for the proposal of Sexual Interest/Arousal Disorder.

DeRogatis claimed that the proposed changes we put forward were “not evidence-based” but are “based upon the opinions of the committee’s members, who have sought support for their nosologic hypothesis from reviews of the literature.” This is quite simply inaccurate. All of the literature reviews were based on a critical appraisal of a great deal of empirical literature; the proposals for revised criteria were made based on these reviews, and certainly not on our “opinions.” DeRogatis stated that “several” recent studies provide support for the idea that hypoactive sexual desire disorder (HSDD) and female sexual arousal disorder (FSAD) are “reliably distinguishable diagnostic entities.” He cited two studies: the first [13] was a study of the reliability of DSM-IV diagnoses of HSDD and FSAD, which demonstrated high

interrater reliability among experts in the field. This study did not evaluate validity, or even clinical utility, of the diagnoses; the fact that there was high interrater reliability is not relevant to the question of whether desire and arousal diagnostic categories should be merged. Although reliability in its many forms is very important, it is not a substitute for validity. Proving that experts consistently rate a defined set of symptoms in the same way does not establish that what they are measuring is a valid category. The second study cited was an as yet unpublished study, reporting differences in FSFI scores between women diagnosed with FSAD and HSDD. We are not surprised that, on the FSFI measure, these two groups differed, as this measure was based on the DSM-IV distinction between desire, arousal, lubrication, and orgasm domains. This research simply proves that the FSFI reliably measures the DSM-IV-TR categories of sexual dysfunction in women. In fact, other studies have found substantial overlap between the desire and arousal FSFI domains (e.g., [14,15]), an observation not mentioned by DeRogatis.

We appreciated the commentaries by Basson and by Laan, Brauer, and van Lunsen. Both of these commentaries made recommendations/suggestions that we want to consider further and highlight that these proposed criteria are very much a “work in progress” and ones for which we welcome feedback/suggestions. Laan et al. noted the vast literature testing the Incentive Motivation Model, which strongly supports desire and arousal as two facets of the same (sexual) coin. These authors went further, however, in suggesting that female orgasmic disorder should also be merged with sexual interest/arousal disorder. We agree that, in clinical practice, the mixed presentation of impaired desire, arousal, and orgasm is common. However, unlike the considerable literature showing overlap between desire and arousal, there is relatively less evidence supporting the overlap between desire/arousal problems and orgasm difficulties. As the DSM-V will be a “living document,” which will be subject to revision as needed, we hope that researchers will empirically study this question of whether desire, arousal, and orgasm disorders are indeed manifestations of the same entity. Laan and colleagues also suggested making the criterion “desire is not triggered by any sexual/erotic stimulus” in sexual interest/arousal disorder a required criterion. This is a question that will be empirically evaluated in the context of our planned field trials, which are scheduled to be completed by the end

of 2010 (Similarly, the question of whether four symptoms out of a possible six is the most sensitive and specific combination for sexual interest/arousal disorder is something we will be able to address following our field trials.). Laan and colleagues also raised the important point that sexual difficulties that are due to inadequate stimulation (e.g., poor partner technique or insufficient knowledge) should not be categorized as sexual dysfunctions. On the basis of this point, our subworkgroup will include the phrase “consideration should be given to context” in the proposed diagnostic criteria for sexual interest/arousal disorder as well as female orgasmic disorder.

Some of the points made in the other commentaries are also deserving of comment. Guay commented on the need for American insurance companies to accept and cover sexual diagnoses. It is critical to emphasize that revisions to the DSM-V are not meant to be influenced by industry—neither an effort to reduce nor create more space for industry. Moreover, changes to diagnoses should not be motivated by the needs of insurance companies. Regarding the latter, we wish to remind readers that the DSM is an international document, not one solely used by American clinicians needing a code to be reimbursed for services. Davis criticized our proposed 75% frequency criterion for sexual interest/arousal disorder and female orgasmic disorder as being “clinically of no value” and impossible to measure. We agree that 75% might be considered arbitrary, although it is based on the “almost always” response option given in nearly every epidemiological survey of sexual dysfunctions. However, as noted earlier, there has been extensive criticism of earlier versions of the DSM for poorly operationalized criteria [16–18] and for the danger of pathologizing normal variations that might be considered adaptive. Setting a requirement that the symptom has occurred on 75% or more of experiences will help to reduce the occurrence of false positives.

Regarding the proposed genito-pelvic pain/penetration disorder criteria, we agree with the comment by Goldstein, Pukall, Kellogg, and Burrows that the proposed minimum diagnostic requirement of a 50% occurrence of pain during intercourse is arbitrary and too high. Unfortunately, there are no currently available data for both superficial and deep dyspareunia that we can currently use to help us decide on an appropriate diagnostic boundary. We are not unhappy with the suggestion of 33% but suspect that many will

legitimately find this frequency of occurrence too high as well. We are still struggling with the appropriate criteria and may ultimately leave such diagnostic boundary decisions to clinician judgment. We would caution these commentators, however, that it is still premature to classify dyspareunia or any form of genito-pelvic pain based on mechanism(s). Hopefully, this will be possible one day but none of the promising cited research findings have been independently replicated or have isolated specific populations which have been successfully treated. Furthermore, we are concerned about sweeping and undocumented statements like those by Laan, Brauer, and van Lunsen that "... dyspareunia without any underlying medical condition starts with and is maintained by unaroused penetration" or by Davis that "dyspareunia commonly has an organic cause..." and "... vaginismus is commonly linked to an underlying psychological cause..." since these statements are not substantiated by empirical references and in fact are contradicted by the evidence that we have reviewed [19,20].

In his concluding paragraph, Goldstein noted, "It is our responsibility to protect the women of the world from having their problems lumped in a way that makes providing treatments more difficult rather than less." In formulating our proposed diagnostic criteria, we were very much focused on trying to develop diagnostic criteria that would better inform clinical diagnosis and treatment. Our subworkgroup strongly agrees that our proposed revisions to the DSM-IV-TR must accurately reflect the existing literature and be in the best interests of women. We are confident that our proposals, although imperfect and in need of verification through field trials, are a step closer to improved taxonomy for sexual dysfunctions and move away from outmoded, or unidimensional views of the nature of the sexual response. These proposals will also be reviewed as new data become available. We continue to invite constructive criticism from our colleagues in the field of human sexuality.

In the final critique on women's sexual dysfunction, Sue and Irwin Goldstein conclude by quoting one of Yogi Berra's classic statements: "When you come to a fork in the road, take it." In our view, they cited the wrong "Berraism." We remind them of a more appropriate quote: "If you don't know where you are going, you might wind up somewhere else." With DSM-V, we are indeed at a fork in the road. Rather than acting impulsively and emotionally, it is time to carefully reflect on the

evidence available to make the best scientific decision independent of industry, insurance, and health system concerns. In the long run, this will serve the best interests of both men and women.

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