## **EDITORIAL**



## Premenstrual dysphoric disorder: A controversial new diagnosis

On January 1st, 2022, the controversial diagnosis premenstrual dysphoric disorder (PMDD) was added to the International Classification of Diseases 11th Revision (ICD-11). PMDD is placed under gynecological diseases and can be seen as a severe form of premenstrual syndrome (PMS). PMS is not a recognized diagnosis but is incorporated in the popular language. The loosely defined premenstrual tension syndrome has also been introduced as an exclusion diagnosis to PMDD. To make a diagnosis of PMDD, the symptoms must occur during the luteal phase in most cycles within the past year and must include an affective symptom (eg irritability or depressed mood) and a somatic/cognitive symptom (eg lethargy, joint pain, concentration difficulties). Furthermore, the condition must cause "significant distress". PMDD affects up to 6% of women of reproductive age.<sup>2</sup> The overlap between symptoms of PMDD and mental disorders such as bipolar disease and depression may present a diagnostic challenge for healthcare professionals.

The introduction of PMDD into the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders 5 (DSM-5) in 2013 has been controversial. On the one hand the addition was strongly advocated by patients, psychiatrists and the pharmaceutical industry, on the other hand it was criticized by psychologists and generalists, fearing over diagnosis and pathologization of normal hormonal changes. Among the opponents were feminist scholars who saw the PMDD label as a way of silencing women and as an inappropriate categorization of aspects of ordinary life as a mental disorder. Some argued that a diagnosis of PMDD might be used against women and serve to mask the actual reasons for a woman's rightful anger and distress.

The addition of the PMDD diagnosis was further criticized for being pushed by the pharmaceutical companies. Indeed, a pharmaceutical company funded and participated in a consensus meeting on the definition of PMDD.<sup>3</sup> This allegedly helped convince the FDA of the diagnostic validity of PMDD and consequently led to the approval of antidepressants for the treatment of the disorder, thereby opening a million-dollar market.<sup>3</sup> To make the drug more attractive for women it was repainted in lavender and pink, and the trade name was changed from Prozac to Sarafem. As part of the marketing process, the company created awareness campaigns for the condition, using the slogan "Think it's PMS? It could be PMDD<sup>3</sup>" a campaign which was later criticized by the FDA for trivializing the condition.

Most of these controversies may still apply to the current introduction of PMDD into ICD-11, although the condition is not placed under mental disorders. It can still be argued that women suffering from real injustices and facing problems with their position in the society or in the family could "just get a pill" instead of being taken seriously. Thus, studies showing a correlation between PMDD and abuse and mistreatment at work have been used to argue the case that real problems were the cause of the cyclical symptoms. The introduction of PMDD has been compared to the introduction of the term "hysteria" that was placed on women in the 19th and 20th century who wanted equal rights. PMDD is, by some, still seen as a social construct – a notion which is supported by the different PMDD prevalence estimates in different countries.

Advocates of PMDD argue that the condition exists because there are women who meet the criteria for the disorder and there is a marked clinical benefit of treatment with hormonal contraception and antidepressants. Furthermore, neurobiological studies have shown a pathological response to hormone fluctuations in women with PMDD.<sup>5</sup> The biological explanation is backed up by newer studies showing that sex-hormone fluctuations may provoke depressive episodes.<sup>6</sup> Opponents argue that little is known about the condition, and that most of the knowledge of PMDD is an extrapolation from studies on PMS.

Advocates of PMDD further state that by acknowledging the condition more research could be done.<sup>3</sup> We recognize the fact that agreement on definitions is important for research, but it should be kept in mind that labelling a woman with a diagnosis may have considerable social and juridical implications. There is still concern that PMDD is not accurately defined and that the distinction between PMS and depression is blurred. To ensure correct diagnosis, prospective registration of symptoms in a diary is recommended.

In 2003, the European Medicines Agency rejected PMDD as an indication for treatment with antidepressants after reviewing the evidence even though a few member countries had approved the indication. The major argument was that PMDD was not a recognized diagnosis in the ICD. With the addition of PMDD into ICD-11, an approval of antidepressants for the treatment of PMDD in Europe may follow. The next step may be advertisements and awareness campaigns as seen in the USA.

There is always a risk of erroneously diagnosing a patient with the wrong condition. In the case of PMDD misdiagnosing a woman

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carries the risk of initiating an unnecessary use of antidepressants that have many adverse effects, such as sexual dysfunction, and may be addictive.

We recognize that PMDD may have a serious impact on a woman's quality of life. As clinicians we are familiar with the stories of women who have felt misunderstood for years, describing that their symptoms have been neglected as usual hormonal changes. These women have a need for formal recognition of the - often debilitating - condition. For many of them it is a relief to finally be taken seriously and receive a diagnosis. However, receiving a diagnosis can also - in some cases - be unhelpful. 8

We must find a proper balance between acknowledging and caring for the sick and at the same time protecting the healthy from overdiagnosis and overtreatment. The introduction of PMDD into ICD-11 may have implications for marketing from pharmaceutical companies, public opinion regarding the condition and activities in patient organizations. To avoid overdiagnosis and unnecessary treatment, it is important that gynecologists (and other physicians) focus on the principle of "primum non nocere" and strictly adhere to ICD-11 definitions while making a diagnosis of PMDD.

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