ORIGINAL RESEARCH—EJACULATORY DISORDERS

Changing Paradigms from a Historical DSM-III and DSM-IV View Toward an Evidence-Based Definition of Premature Ejaculation. Part I—Validity of DSM-IV-TR

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DOI: 10.1111/j.1743-6109.2006.00275.x

ABSTRACT

Background. In former days, information obtained from randomized well-controlled clinical trials and epidemiological studies on premature ejaculation (PE) was not available, thereby hampering the efforts of the consecutive DSM Work Groups on Sexual Disorders to formulate an evidence-based definition of PE. The current DSM-IV-TR definition of PE is still nonevidence based. In addition, the requirement that persistent self-perceived PE, distress, and interpersonal difficulties, in absence of a quantified ejaculation time, are necessary to establish the diagnosis remains disputable.

Aim. To investigate the validity and reliability of DSM and ICD diagnosis of premature ejaculation.

Methods. The historical development of DSM and ICD classification of mental disorders is critically reviewed, and two studies using the DSM-IV-TR definition of PE is critically reanalyzed.

Results. Reanalysis of two studies using the DSM-IV-TR definition of PE has shown that DSM-diagnosed PE can be accompanied by long intravaginal ejaculation latency time (IELT) values. The reanalysis revealed a low positive predictive value for the DSM-IV-TR definition when used as a diagnostic test. A similar situation pertains to the American Urological Association (AUA) definition of PE, which is practically a copy of the DSM-IV-TR definition.

Conclusion. It should be emphasized that any evidence-based definition of PE needs objectively collected patient-reported outcome (PRO) data from epidemiological studies, as well as reproducible quantifications of the IELT.

Waldinger MD, and Schweitzer DH. Changing paradigms from a historical DSM-III and DSM-IV view toward an evidence-based definition of premature ejaculation. Part I—Validity of DSM-IV-TR. J Sex Med 2006;3:682–692.

Key Words. History of Sexual Dysfunction; Causes and Treatment of Ejaculatory/Orgasmic Disorders; Premature Ejaculation; DSM-IV-TR; ICD-10; Definition; Evidence Based

Introduction

The consecutive Work Groups on Sexual Disorders of the Diagnostic and Statistical Manual of Mental Disorders (DSM) must have had quite a difficult time in developing a definition of premature ejaculation (PE). The goal of the DSM classification was to rely on well-controlled clinical and epidemiological studies. However, before 1980, when PE was for the first time mentioned and defined in the DSM-III, such well-controlled studies were not available. Confronted with this reality, each Work Group compromised and defined PE in some general descriptive terms.

Historically, the work of Dr. Helen Singer Kaplan [1] has had a major influence on the formulation of criteria for sexual disorders in the

DSM-III, particularly her view that PE should involve a lack of "voluntary" control (R.T. Segraves, 2006, pers. comm.). The DSM-III stated that "Ejaculation occurs before the individual wishes it, because of recurrent and persistent absence of reasonable voluntary control of ejaculation and orgasm during sexual activity" [2]. This part of the definition was changed in the DSM-III-R, in which the issue of voluntary control was removed and PE became defined as "persistent or recurrent ejaculation with minimal sexual stimulation or before, upon, or shortly after penetration and before the person wishes it" [3]. However, by using this definition, it is the clinician who, according to the DSM-III-R, "must take into account the factors which affect the duration of the excitement phase, such as age, novelty of the sexual partner or situation, and frequency of sexual activity" [3]. The DSM-III-R uses a typical descriptive definition of PE which, like the DSM-III definition, resembled that of a formerly published definition in 1969 by Alan J. Cooper, who formulated PE as "the persistent occurrence of orgasm and ejaculation either before, or immediately following penetration of the female during coitus, occurring against volition and before the male wishes it" [4]. A new extended definition in the DSM-IV (1994) required that "The disturbance causes marked distress or interpersonal difficulty" [5]. However, realizing that each consecutive DSM definition of PE is built on the opinion of expert authorities and not on evidence-based research raises questions about the validity and reliability of this definition.

In this article, the historical development of the DSM and DSM criteria for PE is critically reviewed. In part II, proposals for an evidence-based medical definition are outlined.

DSM-I and DSM-II

The first two editions of the DSM, published in 1952 and 1968 respectively, did not include sexual disorders but only "sexual deviations" such as pedophilia and at that time also homosexuality [6,7]. Aside from a vague category "psychophysiologic genito-urinary disorder" in the DSM-II, ejaculatory disorders were not mentioned.

It was only in the DSM-III, published in 1980, that psychosexual disorders were included in the classification system. The definition of PE as stated in the DSM-III has undergone only minor changes in the later editions: DSM-III-R, DSM-IV, and DSM-IV-TR (see Addendum).

DSM-III and DSM-IV Definition of PE

In recent years, based on scientific evidence, it increasingly appeared that the current DSM definition has become insufficient for clinical practice and research purposes [8–10]. However, in the need for a definition of PE that is based on facts and figures, a strange paradox has emerged. Despite the fact that scientific arguments were made to reject the DSM definition, one created surrogate markers to keep up with the everlasting DSM dogmas, i.e., Self-perceived PE, Satisfaction, Distress, and Control. These surrogate markers became more and more accepted as essential for the clinical definition of PE [11]. Another option would have been to include a quantification of the ejaculation time into the definition and to take reproducible cut-off points to decide what is normal vs. abnormal.

It should be noted that in 2004, the latest DSM definition became accepted, albeit in more brief wording, by the American Urological Association's (AUA) Guideline on the Pharmacologic Management of PE, which stated that "Premature ejaculation is an ejaculation that occurs sooner than desired, either before or shortly after penetration, causing distress to either one or both partners" [12]. It should be emphasized that this definition, like its original source in the DSM, lacks any basis in systemic research. Therefore, for scientific reasons, this AUA definition of PE is far from evidence based and also needs more adjustment to fulfill the modern needs of a scientific approach [13,14]. For a better understanding of how DSM definitions in general were developed, a historical synopsis from originally mainly authority-based opinions toward evidence-based standards, is described in the following paragraphs.

Historical Background

DSM-I (American Psychiatric Association, 1952)

The first edition of the DSM was developed by a committee of leading clinicians and researchers on the basis of their own clinical experiences and their implicit understanding of the existing literature [6,15,16]. The DSM-I committee (chaired by George Raines) submitted a draft of definitions, which has been sent to 10% of the membership of the American Psychiatric Association (APA), but no specific results of this survey were reported [17].

DSM-II (American Psychiatric Association, 1968)

DSM-II was constructed by a process similar to DSM-I. A committee of leading clinicians and researchers (chaired by Ernest Gruenberg) re-

viewed proposed revisions and reached a consensus [7]. A draft was sent to 120 psychiatrists with a special interest in diagnosis, but again, specific results were not published [17].

DSM-III (American Psychiatric Association, 1980)

In 1974, the APA appointed a committee (chaired by Robert Spitzer) to revise DSM-II in a manner that would incorporate research innovations [2,18]. A draft of DSM-III was published in 1978, but no systematic survey of support for the proposals was conducted. The APA acknowledged that there was virtually no systematic research for many of the criterion sets and inadequate research support for all but a few definitions. They stated that for most of the categories, the diagnostic criteria were based on clinical judgement (APA, 1980, p. 8) [2].

"Thus, the subjective judgement of the members of the task force played a crucial role in the development of DSM-III, and differences of opinion could only rarely be resolved by appeal to objective data" (Spitzer, 1985, p. 523) [19]. Spitzer further acknowledged that "because appeals to objective data for resolving nosologic controversies were relatively rare, speaking and writing skills (rhetoric) played an important role in resolving controversies" (1985, p. 523) [19]. DSM-III introduced a number of important methodological innovations, including explicit diagnostic criteria, a multiaxial system, and a descriptive approach that attempted to be neutral with respect to theories of etiology [17].

DSM-III-R (American Psychiatric Association, 1987)

Soon after the publication of DSM-III, a number of problems with the criterion sets became evident. The APA (1987) indicated that there were "many instances in which the criteria were not entirely clear, were inconsistent across categories, or were even contradictory" (p. xvii) [3]. Therefore, in 1983, the APA appointed a work group (chaired by Robert Spitzer) to make corrections and clarifications. This time the field trials focused on validity as well as reliability. "The purpose of these field trials was to examine the feasibility of proposed criteria for the disorders and to determine the optimal number of items to require for maximizing sensitivity and specificity, using clinician's diagnoses as the criterion" (Spitzer and Williams, 1988, p. 872) [17,18].

DSM-IV (American Psychiatric Association, 1994)

In 1988, the APA appointed a committee (chaired by Allen Frances) to begin work on DSM-IV. The DSM-IV committee aspired to use a more conservative threshold for the approval of new diagnoses and to have the decisions be guided more explicitly by the scientific literature [20]. Frances et al. (1989) suggested that "the major innovation of DSM-IV will not be in its having surprising new content but rather will reside in the systematic and explicit method by which DSM-IV will be constructed and documented" (p. 375) [21]. Proposals for additions, deletions, or revisions were guided by 175 literature reviews. Testable questions that could be addressed with existing data sets were also explored in 36 studies [22]. Finally, 12 field trials were conducted to provide reliable and valid data on proposed revisions [17,20].

DSM-IV-TR (American Psychiatric Association, 2000)

In 1997, the APA appointed the DSM-IV Text Revision Work Groups (chaired by Michael B. First) to revise the DSM-IV. Because of the risk that the information in the DSM-IV, which was prepared on the basis of literature dating up to 1992, ran the risk of becoming increasingly out-of-pace with the large volume of research published each year, a revision of the DSM-IV text was undertaken, with the aim to correct any factual errors that were identified in the DSM-IV text, to ensure that all of the information was still up-to-date, and to add new information that was published after 1992. All changes proposed for the text had to be supported by empiric data (DSM-IV-TR, pp. xxix–xxx) [23].

International Classification of Diseases (ICD)-9 and ICD-10

The development of the DSM-III and DSM-IV editions was coordinated with the 9th and 10th development of the International Classification of Diseases (ICD) of the World Health Organization (WHO) [24–27]. In the early 1960s, the WHO became actively engaged in improving the diagnosis and classification of mental disorders in the ICD. However, in the ICD-9 (1975), PE was not specifically mentioned [24]. PE was meant to be categorized under the code V41.7 ("Problems with sexual function"). In the Clinical Modification version, ICD-9-CM, published in 1978, PE was still not specifically defined but for the first time categorized as a term under the code 302.75, meaning "psychosexual dysfunction with premature ejaculation (ejaculatio praecox)" [25].

It was only in 1992 that PE became for the first time defined as a separate "mental disorder" in the ICD-10 under the heading "Sexual dysfunction,

not caused by organic disorder or disease (code F52)" [26]. However, the ICD-10 used two different definitions of PE. In the ICD-10 version "Clinical Description and Diagnostic Guidelines," PE (code F52.4) is defined as "The inability to control ejaculation sufficiently for both partners to enjoy sexual interaction. In severe cases, ejaculation may occur before vaginal entry or in the absence of an erection. PE is unlikely to be of organic origin but can occur as a psychological reaction to organic impairment, e.g., erectile failure or pain. Ejaculation may also appear to be premature if erection requires prolonged stimulation, causing the time interval between satisfactory erection and ejaculation to be shortened; the primary problem in such a case is delayed erection" [26]. In addition, the ICD-10 specifies a minimum duration of at least 6 months of symptoms. However, in the ICD-10 version "Diagnostic criteria for research," PE (code F52.4) is defined, also under the heading "Sexual dysfunction, not caused by organic disorder or disease (F52)" but now by three criteria (A, B, and C) [27].

A The general criteria for sexual dysfunction (code F52) must be met, i.e., G1: The subject is unable to participate in a sexual relationship as he or she would wish; G2: The dysfunction occurs frequently, but may be absent on some occasions; G3: The dysfunction has been present for at least 6 months; and G4: The dysfunction is not entirely attributable to any of the other mental and behavioral disorders in ICD-10, physical disorders (such as endocrine disorders), or drug treatment. Moreover, it is commented that "Measurement of each form of dysfunction can be based on rating scales that assess severity as well as frequency of the problem. More than one type of dysfunction can coexist."

B There is an inability to delay ejaculation sufficiently to enjoy lovemaking, manifest as either of the following:
   (1) occurrence of ejaculation before or very soon after the beginning of intercourse (if a time limit is required: before or within 15 seconds of the beginning of intercourse);
   (2) ejaculation occurs in the absence of sufficient erection to make intercourse possible.

C The problem is not the result of prolonged abstinence from sexual activity.

In summary, in the ICD-9-CM (1978), PE was for the first time mentioned as a separate sexual dysfunction in a disease classification system, but not further defined or operationalized. Its first official "definition" was published 2 years later in the DSM-III (1980). Interestingly, in contrast to the DSM definition, the ICD-10 version "Diagnostic criteria for research" uses a cut-off point for the ejaculation time of 15 seconds, but does not provide literature on which this quantification is based.

There is also another remarkable difference between the DSM-IV and the ICD-10. In the DSM-IV, PE has to cause marked distress and/or interpersonal difficulty before it can be termed a (mental) disorder. However, in the ICD-10, interpersonal difficulties are not mentioned. Here, a subject "should be unable to participate in a sexual relationship as he or she would wish" before it can be termed a sexual dysfunction [27,28].

Inconsistencies in the DSM Definition of PE

The descriptive definition of PE by the DSM clearly interferes with other ejaculatory dysfunctions. The insight in different ejaculation mechanisms, as well as in how ejaculation time is distributed among the general male population, was not available due to lack of evidence-based clinical studies. Members of the DSM-IV Working Group on Sexual Disorders were confined to historical views expressed by authorities, and some of the members had expressed their concern about the DSM-accepted criteria for sexual diagnoses [R.T. Segraves, 2006, pers. comm., 10]. They argued that these criteria lacked specification of critical elements such as frequency, duration, and severity [R.T. Segraves, 2006, pers. comm., 10]. The DSM-IV Task Force demanded evidence-based data for any change in the existing criteria. However, as such data were not available at that time, neither changes of criteria nor operational definitions were proposed [R.T. Segraves, 2006, pers. comm., 10]. In the following paragraphs, we will outline major inconsistencies of the current DSM definition of PE.

Ejaculation and Orgasm

Ejaculation and orgasm usually occur simultaneously during the male sexual act but are probably confined to at least two separate biological circuits. Ejaculation occurs in the genital organs, whereas orgasmic sensations, albeit related to the genitals "in operation," are mainly a cerebral event [29–31]. Independent occurrence of ejaculation and/or orgasm may occur in rare clinical syndromes. For example, men with anesthetic ejaculation experience a normal ejaculation, but suffer

from an absence of orgasmic sensations, while men with PE experience a far too early ejaculation with a completely intact orgasmic sensation [32]. In the DSM-IV (APA, 1994), ejaculatory and orgasmic disorders are both mentioned under the heading of "Orgasmic Disorders." Strangely, in the DSM-IV, retarded ejaculation has been called "male orgasmic disorder," analogous to "female orgasmic disorder," whereas PE has not been called "premature male orgasmic disorder" [33]. Furthermore, the aforementioned anesthetic ejaculation and a rare syndrome called partial ejaculatory incompetence have never been defined in the DSM-IV [30,34].

Marked Distress or Interpersonal Difficulty

For a better understanding of how "marked distress and interpersonal difficulty" has become an overall requirement for DSM definitions, some insights about its history will be shortly reviewed. First of all, it should be realized that the DSM uses "distress" in two different ways: as part of the definition of a mental disorder, and on the other hand, as criterion B of dysfunctions to be considered, a disorder according to the DSM-IV and DSM-IV-TR. In a chapter on classification in psychiatry, Zimmerman and Spitzer provided interesting information on how "distress" has become incorporated in the first definition of a mental disorder in the DSM-III [35]. In the DSM-II, in which a mental disorder was not specifically operationally defined, homosexuality was classified as a mental disorder under the heading of "sexual deviation" [7]. In 1973, Robert Spitzer and many psychiatrists wanted to remove the "mental disorder" homosexuality from the DSM-II. To justify this removal, Spitzer proposed to provide a definition of a mental disorder: "A mental disorder is conceptualized as a clinically significant behavioral or psychological syndrome or pattern that occurs in an individual and that is typically associated with either a painful symptom (distress) or impairment in one or more important areas of functioning (disability)" [2]. With this definition, Spitzer argued that homosexuality per se does not satisfy the two requirements of his definition, because "many homosexuals are quite satisfied with their sexual orientation and demonstrate no generalized impairment in social effectiveness or functioning" [35]. As a consequence of this definition of a "mental disorder," homosexuality was no longer regarded as a mental disorder and not any longer classified as a sexual deviation (R.L. Spitzer, 2006, pers. comm.). But homosexuality was still mentioned in the DSM-III, albeit in another form. Although "ego-syntonic" homosexuality was no longer regarded as a mental disorder, "ego-dystonic" homosexuality became classified under the heading of "Other psychosexual disorders." In the DSM-IV and DSM-IV-TR, homosexuality was no longer mentioned.

Apart from the aforementioned debate on homosexuality as a mental disorder, the DSM-III-R required "distress" to become a part of the definition of the various "paraphilias" but not of other "sexual dysfunctions" like PE [3]. For example, criterion B of "pedophilia" required that a person has pedophilia if "the person has acted on these urges, or is markedly distressed by them." Obviously, this requirement created a major problem in the diagnosis of pedophilia, as it only became a disorder if the patient was distressed by it. However, the difficulty that was raised by the requirement of "distress" in the diagnosis of the various "paraphilias" became rather unnoticed by the decision of the DSM-IV Task Force to apply the requirement of "marked distress" explicitly to all disorders in the DSM-IV, including the definition of PE. This criterion B of "marked distress and interpersonal difficulty" was introduced to all mental disorders in the DSM-IV, as the DSM-IV Task Force feared the potential risk of false-positive diagnoses by an increasing number of new diagnostic categories [5]. In order to help establish the threshold for the diagnosis of a disorder in those situations in which the symptomatic presentation by itself (particularly in its milder forms) is not inherently pathological, it was argued that "marked distress" should become a required criterion for any diagnosis [23]. In other words, due to the debate on how to reduce the problem of potential overdiagnosis and in contrast to the initial definitions of PE in the DSM-III and DSM-III-R, the DSM-IV and DSM-IV-TR requires the coexistence of "marked personal distress and interpersonal difficulties" for the diagnosis of PE. However, these requirements are odd against the background of the neurobiological nature of the problem. For example, migraine is nothing else but headache that coincides with typical neurophysiological features, regardless of any personal distress or interpersonal difficulties. Moreover, there are many men with PE without marked personal distress and/or interpersonal difficulties and who cope well with their sexual problem. And what about men who at a younger age cope well with their rapid ejaculation time, but become annoyed later in life by it in spite of the fact that their

ejaculation time has remained similar? Would it be fair to diagnose these men to suffer from PE based on their "distress" during later life, while excluding them from this diagnosis as they were younger? Unfortunately, according to the DSM-IV definition, the answer should be yes, in contrary to the clinical judgment in migraine. No experienced neurologist would ever diagnose migraine only if the headache is accompanied by inter- or personal distress. In 1994, it was difficult for the DSM-IV Task Force to anticipate that their decision to apply "marked distress and interpersonal difficulty" to all disorders in the DSM would have unfortunate consequences for the understanding of some of the sexual disorders, especially PE.

Above-mentioned examples hopefully clarify our proposition, which we have proposed also previously, to abstain from the "marked personal and interpersonal distress" into the definition of PE [36,37].

Self-Perceived PE

The DSM criterion of ejaculating "before the individual wishes it" implies that the diagnosis becomes dependent on the subjective experience of the male subject. In other words, an objective time measurement is regarded as irrelevant. The following study, although not aimed at investigating this issue, illustrates the consequences of such a subjective approach. In an Internet survey, sponsored by ALZA Corporation, Rowland et al. [38] distinguished men with PE and without PE by using the DSM-IV-TR definition, meaning that time was not objectively measured.

By asking two questions "Do you ejaculate before you wish in more than 50% that you have sexual intercourse? (yes/no)" and "How much of a problem is this for you (none, a little, somewhat, very much)?", they reported that 377 out of 1,158 men (32.5%) ejaculated "before they wished." This percentage is in agreement with the prevalence data that have been found in other studies [39,40]. However, by making a diagnosis of PE and non-PE according to these subjective criteria, it is highly probable that selection bias has been introduced into the study. In the first place, each individual who did not complain about his ejaculation time was automatically assigned to the group of men without PE, regardless of how rapidly they actually ejaculated. Second, each individual who complained was considered as a premature ejaculator despite the fact that an objective measurement of the ejaculation time was ignored. The selection bias also implies that individuals who are capable of coping well with their short ejaculatory time will not be assigned to the PE group with definite consequences in case of a drug treatment trial. The same holds true for those individuals who complain, regardless of their ejaculation time.

Another selection bias may be the obligatory DSM requirement of "distress and interpersonal difficulty," represented by the question "how much of a problem is the undesired rapid ejaculation time for you?" From the 377 men, 49.8% expressed that they had no or few problems from it, in 36.3% it was somewhat a problem, and in 13.7% it was very much a problem. These percentages demonstrate that only a part of the complainers really suffered from it. Moreover, these results also clarify that only a small part of complainers will seek medical treatment. One should therefore be cautious of campaigns by pharmaceutical companies explaining that the minority of men seeking medical treatment should be ascribed to a lack of information about the availability of ejaculation-delaying drugs. A reanalysis of the aforementioned data revealed that only 33.9% of all 377 men with self-perceived PE reported that their ejaculatory control was poor to very poor. This low percentage contradicts the outcome of a previous study by the same author, stating that 88% of PE men are unable to "exert any control over ejaculation" [41]. Unfortunately, their current study did not report the level of control of the men diagnosed as non-PE.

Age and Novelty of Sexual Partner

The DSM-IV and DSM-IV-TR state that "The clinician must take into account factors that affect duration of the excitement phase, such as age, novelty of the sexual partner or situation, and recent frequency of sexual activity." In this respect, only one study investigating validation aspects of the DSM-IV diagnostic criteria has been previously published [9]. In this study, among 110 men and their woman sexual partners, no correlations were found between age and self-perceived IELT, stopwatch-assessed IELT, and frequency of intercourse. The stopwatch-assessed IELT was not correlated with the duration of the relationship, which was used as a measure of partner novelty. However, the stopwatch-assessed IELT was moderately correlated with the frequency of intercourse ($r = 0.32$; $P < 0.001$). In other words, apart from its face validity, no evidence could be found for the validity of these DSM requirements for the

clinician to take into account. The only moderate correlation between the IELT and frequency of intercourse i.e., the longer the baseline IELT, the greater the frequency of intercourse, probably represents the tendency to avoid intercourse by both men and women when the man partner has PE [9].

Control

Mainly in the view of and due to the authority of Dr. Helen Singer Kaplan, the DSM-III definition of PE used lack of "voluntary control" (R.T. Segraves, 2006, pers. comm.). However, others have argued somewhat later that men with PE do not necessarily suffer from a lack of "voluntary control" but from "involuntary lack of control" (R.T. Segraves, 2006, pers. comm.). Apart from the first definition in the DSM-III, "lack of voluntary control" was no longer used in the later editions DSM-III-R, DSM-IV, and DSM-IV-TR (see Addendum). However, the domain "control" became gradually implied into patient-reported outcomes (PROs), which were designed to diagnose PE. Control is also a part of the ICD-10 definition of PE.

The use of the word "control" started with the definition by Masters and Johnson in 1970, who defined a man as a premature ejaculator if "he cannot *control* his ejaculatory process for a sufficient length of time during intravaginal containment *to satisfy* his partner in at least 50 percent of their coital connections" [42]. Moreover, Masters and Johnson decided to reject any definition using the measurement of ejaculation time. For example, they abstained from a well-known definition —at that time—for a premature ejaculator as "a man who cannot control his ejaculatory process for at least the first 30 seconds after penetration or 1 minute of intravaginal containment" [42]. Masters and Johnson stated specifically that "at least their definition does move away from the 'stopwatch' concept." In other words, Masters and Johnson firmly expressed their insight to disconnect "control" from "the duration of the ejaculation time," while propagating that "control" should be connected to the "satisfaction" of the woman partner. In this way, the domain "satisfaction," albeit from the woman partner, became part of the definition of PE. Notably, Masters and Johnson never provided evidence to support their definition of PE [43]. On the contrary, they have always emphasized that it is not the time of ejaculation but particularly "control and satisfaction" that are relevant to establish the diagnosis of "PE." Their dogma has not been changed until today [37]. Today, the concept of control is still related to satisfaction but may also mean no control over the moment of imminent ejaculation. The subjectivity and various meanings of feelings of control make this concept difficult for operationalization and too vague for single use in a definition.

A recent study by Patrick et al. [44] illustrates how the definition of PE, according to the DSM-IV-TR with three added PROs, i.e., Control, Satisfaction, and Distress, can lead to an incorrect diagnosis. In this observational multicenter study in the United States, experienced clinicians in the PE field were asked to classify men whether suffering from PE or not. Each physician based his or her clinical judgment on the DSM-IV-TR criteria added with the domains Control, Satisfaction, and Distress. Ejaculation time was not a criterion to establish the diagnosis of PE. Nevertheless, each subject was requested to measure his IELT with a stopwatch while having intercourse during a period of 4 weeks. It is of note that the cohort of men was not random, as a selection was established by various inclusion and exclusion criteria. The study was sponsored by Johnson & Johnson that paid each participating couple about 400 dollars. All 1,587 couples were asked to fill out a questionnaire about single-item PROs about control over ejaculation, satisfaction with sexual intercourse, personal distress, interpersonal difficulty, and severity of PE. The diagnosis of PE was graphically represented in 190 men, while the remainder 1,215 men did not meet the DSM-IV-TR criteria for PE. It was found that the median IELT of men with PE (median 1.8 minutes) was significantly shorter than that of men with non-PE (median 7.3 minutes), both with a wide range of 0–25 minutes. However, it appeared that there was a considerable overlap of the IELTs between both groups. A lot of men diagnosed as having PE appeared to have IELTs longer than the median of 1.8 minutes. Moreover, there were also men diagnosed as having non-PE who had IELTs below the median of 1.8 minutes.

A reanalysis of their plotted data illustrated that an IELT threshold of both 1 and 2 minutes did not discriminate among men who were diagnosed with or without PE, meaning that 26% and 52% of the PE group ejaculated within 1 and 2 minutes, respectively. In other words, half of the by-the-DSM-IV-TR-identified PE group ejaculated after 2 minutes. Moreover, some 35% and 13% of the complainers ejaculated within 2–5 and 5–

25 minutes, respectively. Of the non-PE men, 6% ejaculated within 2 minutes. This study also shows that anybody diagnosed as having PE according to the DSM criteria has a 48% risk that this diagnosis is incorrect if a 2-minute cut-off point of the IELT was used. One can say therefore that the DSM definition of PE, being the discriminative test to distinguish PE from non-PE, implies a positive predictive value of (only) 52% and a negative predictive value of 94% in terms of a real-time rapid ejaculation. To summarize, the power of a complaint to predict a short ejaculation time appears to be inferior to what is generally accepted as a reliable test. It may be concluded that linking ejaculation time to the DSM criteria (control, satisfaction, and stress estimates) will not generate a useful tool to predict objective dysfunction. By abolishing time measurement into the DSM definition, the message of this study confirms that no solid methodological design was originally used to establish the criteria of PE in the DSM-III. Practically, our reanalysis emphasizes the need for a definition comprising ejaculation time measurement together with subjective complaints.

Although Patrick et al. [44] acknowledged the experience of the clinicians in diagnosing PE according to the DSM criteria, kappa values indicating the accuracy of the clinicians to diagnose PE were not mentioned in their work. In contrast to our conclusions, Patrick et al. [44] concluded that the test of real-time measurement of the IELT was not robust enough to establish the diagnosis "PE," implicating that the DSM criteria of PE were superior and that PROs should be applied to diagnose PE. However, this would implicate that even men who complain of rapid ejaculation and who ejaculate between 5 and 25 minutes can be diagnosed as suffering from PE as their study has so clearly demonstrated. Although such a diagnosis would be incorrect, it still remains in agreement with the concepts of Masters and Johnson, who emphasized the issue of the suffering man complaining from discontentment regarding his ejaculatory performance. It is also in agreement with the DSM-IV-TR and AUA definitions of PE, as both definitions do not provide a cut-off point of the ejaculation time.

However, in our opinion and based on our reanalysis of the study of Patrick et al. [44], the latter authors unintentionally demonstrated that too much emphasis on PROs, such as the subjective experience of ejaculation time, control, and satisfaction, and psychological distress without taking into account the duration of the ejaculation time, leads to the inappropriate diagnosis of PE.

Validity of DSM Definition

Critical notes can be made about reliability and validity issues of the DSM definition of PE. For example, inclusion and exclusion criteria necessary to establish the diagnosis "PE" have never been mentioned in the DSM [8,10]. The sole diagnostic criterion used in the definition is "persistent or recurrent ejaculation with minimal sexual stimulation before, upon, or shortly after penetration and before the person wishes it." Moreover, "physicians should be informed about the factors that affect duration of the excitement phase, i.e., age, novelty of the sexual partner or situation, and frequency of sexual activity" (see Addendum).

The DSM, however, does not educate the reader in how to use these factors. The interpretation of what is meant by "persistent," "recurrent," "minimal," and "shortly after" remains unclear [8,43]. The same holds true for the interpretation of "a person's wishes." Finally, there are no clear criteria mentioned for lifelong vs. acquired PE.

Critical methodological objections against the diagnostic criteria of several sexual dysfunctions by the DSM-III have been made previously by O'Donohue et al. [8]. In spite of the high kappa coefficients of near 1.0 found for general psychosexual disorders and dysfunctions based on several field trials including 339 subjects [2], such kappa coefficients mean nothing else but interrater reliabilities for a wide variety of diagnostic categories rather than for detailed diagnoses. Thus, firm agreements can be reached for the kind of psychosexual disorder or sexual dysfunction without firm agreements about the exact diagnosis. Second, the information about these high kappa coefficients appears to be statistically invalid because of the very small sample sizes for each specific diagnosis, relying on very few numbers [8].

Conclusion

The various DSM Work Groups of Sexual Disorders have remained unable to develop an operational definition of PE, mainly as a result of the lack of controlled clinical and epidemiological studies. Instead, they were only able to formulate a descriptive definition of PE. Due to a lack of explicit quantitative requirements and due to the vague descriptions, the DSM-IV-TR definition of PE is inappropriate for both daily clinical practice

and epidemiological or drug treatment research. Recent studies using the DSM-IV-TR criteria to establish the diagnosis of PE and non-PE demonstrated that exclusion of an objective time assessment of the IELT would lead to selection bias as the result of a low positive predictive value of the DSM definition and by just asking for complaints. Such a definition reveals nothing else but a high percentage of false-positive diagnoses. The DSM requirement of "marked distress and interpersonal difficulty" for establishing the diagnosis of mental disorders in general, including that of PE, has not been based on clinical studies and may therefore be confounding factors. Ironically, the requirement of "marked distress and interpersonal difficulty," originally meant by the DSM-IV Task Force to reduce the risk of false-positive diagnoses in general, appears to increase the risk of false-positive diagnoses of PE. The DSM-IV-TR and the similar AUA definitions of PE are not based on systematic research but merely on authority-based views collected from members of the Task Force. An evidence-based definition of PE should be based on objective data of systematic research together with a quantification of the ejaculation time.

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Conflict of Interest: None.

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Addendum Part I

DSM Definitions of Premature Ejaculation

DSM-III (APA 1980; 302.75; p. 280)
Diagnostic Criteria

A Ejaculation occurs before the individual wishes it, because of recurrent and persistent absence of reasonable voluntary control of ejaculation and orgasm during sexual activity. The judgement of "reasonable control" is made by the clinician's taking into account factors that affect duration of the excitement phase, such as age, novelty of the sexual partner, and the frequency and duration of coitus.
B The disturbance is not due to another Axis I disorder.

DSM-III-R (APA 1987; 302.75; p. 295)
Diagnostic Criteria
Persistent or recurrent ejaculation with minimal sexual stimulation or before, upon, or shortly after penetration and before the person wishes it. The clinician must take into account factors that affect duration of the excitement phase, such as age, novelty of the sexual partner or situation, and frequency of sexual activity.

DSM-IV (APA 1994; F52.4; p. 524)
Diagnostic Criteria

A Persistent or recurrent ejaculation with minimal sexual stimulation before, on, or shortly after penetration and before the person wishes it. The clinician must take into account factors that affect duration of the excitement phase, such as age, novelty of the sexual partner or situation, and recent frequency of sexual activity.
B The disturbance causes marked distress or interpersonal difficulty.
C The premature ejaculation is not due exclusively to the direct effects of a substance (e.g., withdrawal from opioids).

Specify type: Lifelong Type, Acquired Type
Specify type: Generalized Type, Situational Type
Specify: Due to Psychological Factors, Due to Combined Factors

DSM-IV-TR (APA 2000; 302.75; p. 554)
Diagnostic Criteria

A Persistent or recurrent ejaculation with minimal sexual stimulation before, on, or shortly after penetration and before the person wishes it. The clinician must take into account factors that affect duration of the excitement phase, such as age, novelty of the sexual partner or situation, and recent frequency of sexual activity.
B The disturbance causes marked distress or interpersonal difficulty.
C The premature ejaculation is not due exclusively to the direct effects of a substance (e.g., withdrawal from opioids).

Specify type: Lifelong Type, Acquired Type
Specify type: Generalized Type, Situational Type
Specify: Due to Psychological Factors, Due to Combined Factors