# Changing Paradigms from a Historical DSM-III and DSM-IV View Toward an Evidence-Based Definition of Premature Ejaculation. Part II—Proposals for DSM-V and ICD-11

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DOI: 10.1111/j.1743-6109.2006.00276.x

**ABSTRACT**

***Background.*** In the Diagnostic and Statistical Manual of Mental Disorders (DSM), a descriptive definition for premature ejaculation (PE) that was based on historical assumptions has been accepted.
***Aim.*** To formulate a new functional definition of PE in the DSM.
***Methods.*** A "syndrome" approach instead of a "complaint" approach is applied and evidence-based data from epidemiological and clinical studies are used.
***Results.*** A new functional definition of PE should pertain to a cluster of "symptoms" of a distinct "syndrome." A syndrome rather than a descriptive definition should distinguish Lifelong and Acquired PE variants. Evidence-based data also suggest another PE type "Natural Variable PE," which is not a typical syndrome but rather a cluster of inconsistent symptoms of rapid ejaculation. Moreover, in "Natural Variable PE" the occurrence of rapid ejaculation is not based on neurobiological or psychological pathology, but belongs to the normal variability of sexual performance. Its prevalence is probably much higher than that of Lifelong and Acquired PE. We propose three separate operationalized definitions of these three PE types for the pending DSM-V and ICD-11, which include a quantification of the ejaculation time (intravaginal ejaculation latency time), inability of ejaculatory control, and a description of severity of PE in terms of psychological distress.
***Conclusion.*** The use of the intravaginal ejaculation latency time into the DSM-V and ICD-11 would mean that statistical evidence becomes accepted as one of the mainstays for establishing an evidence-based definition of the three PE types. **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 II—Proposals for DSM-V and ICD-11. J Sex Med 2006;3:693–705.**

***Key Words.*** History of Sexual Dysfunction; Premature Ejaculation; Epidemiology; DSM-V; ICD-11; Definition; Natural Variable PE

## Introduction

As the result of a better understanding of premature ejaculation (PE) and based on drug treatment research showing clear efficacy in the daily use of selective serotonin reuptake inhibitors (SSRIs), there is a growing popular interest in treating PE with medication [1,2]. However, an operational definition of PE distinguishing some various types in detail is so far lacking. Moreover, the most recent edition of the DSM, the DSM-IV-TR, remains vague in explaining the fine distinction of possible diagnostic categories, thereby leaving the field open for speculation [3,4]. In times of evidence-based medicine, an operationalized definition of PE remains mandatory for future drug treatment research and a better understanding of a common complaint in sexually active men.

The introduction of the intravaginal ejaculation latency time (IELT) in 1994 [5] and a baseline measurement of the IELT with a stopwatch

[6] have altered and improved the methodology of drug treatment studies on PE and increased our understanding of psychopharmacology by keeping interventions reproducible and comparable [1,7]. In addition, both well-controlled clinical and epidemiological studies of the IELT using a stopwatch also contributed to a more profound understanding about some quantitative aspects of PE [1,7]. Much evidence-based data have been published quite recently and were therefore never used, even in the latest DSM edition. With reference to the pending DSM-V and ICD-11, it is a challenge to rephrase the current text, meaning that at least a part of the old definitions in sexual medicine would become in agreement with the practice of modern medicine. Revision of the classification and definition of ejaculatory disorders in general is necessary; similar revisions have been previously conducted for psychiatric disorders. In more detail, adjustment of the DSM and ICD definition of PE needs a scientific basis [4].

Premature ejaculation, according to the current DSM criteria, mainly emphasizes "complaints" of a too rapid experienced ejaculation, and personal and interpersonal distress about it. In part I, we described the historical development of the DSM and illustrated the inconsistencies of its definition of PE [4]. In the following paragraphs, we will describe new insights of PE and discuss which implementation may contribute to a new and more evidence-based definition of PE.

#### Development of a Definition

There are two ways to establish the definition of a disorder or dysfunction. The first way is authority-based opinion formulation, followed by investigation of this opinion in clinical practice. The second way is the collection of evidence-based data and reliance on epidemiological studies of random cohorts and randomized clinical trials. The DSM definition of PE is clearly an example of the first way.

Clinical trials using the DSM-IV-TR definition have been performed by Patrick et al. [8] and Rowland et al. [9]. Although it has not been the purpose of these authors, their studies can be used to investigate the validity of the DSM-IV-TR diagnosis [4]. Fortunately, one of these studies also formulated the secondary outcome of stopwatch assessment of the IELT, which facilitated to formulate the positive and negative predictive value of the DSM-IV-TR definition of PE [4]. The outcome of its low positive predictive value revealed that the DSM-IV and DSM-IV-TR definitions may need revision [4]. Consequently, the first way of formulating a definition should be abandoned and replaced by the second way of establishing a definition of a disorder or dysfunction.

#### Development of an Evidence-Based Definition

Definitely in contrast to the view of Masters and Johnson, Waldinger et al. emphasized the clinical relevance of the ejaculation time [1,2,5,10–15]. In 1992 there was no neurobiological and operational definition of PE, and therefore the IELT was introduced and defined as the time between vaginal intromission and intravaginal ejaculation [5,14]. In a meta-analysis referring to studies from 1943 to 2003, it was shown that the IELT assessment with a stopwatch was superior, as compared with spontaneous reporting and questionnaire studies in precisely assessing the ejaculation time [1]. Implementation of the IELT in randomized clinical trials facilitated the interpretation of drug treatment protocols and comparison of different active drugs, and contributed much to an evidence-based approach of drug treatment trials [1,7]. In a clinical study looking at men who were selected according to their complaints, it was demonstrated that 80% of men with lifelong PE ejaculated within 30 seconds and that 10% ejaculated between 40 and 60 seconds [10]. The remaining 10% ejaculated between 1 and 2 minutes [10]. These outcomes were registered in a group of men who have decided on their own to seek medical treatment in a tertial referral center for sexual disorders. From these outcomes the question was raised about the prevalence of ejaculatory latencies among the general healthy male population. In 2005, Waldinger et al., sponsored by Pfizer Int., conducted a stopwatch study in a random cohort of 491 men among five countries (the Netherlands, the United Kingdom, Spain, Turkey, and the United States) [12]. Participants were not financially reimbursed for their participation. Moreover, in order to get a genuine random cohort of men, inclusion and exclusion criteria were not applied. Also in this general male population, the natural IELT distribution was positively skewed to the right, with a median IELT of 5.4 minutes (range 0.55–44.1 minutes) [12,13].

Based on this type of distribution, percentiles were formulated to establish reasonable cut-off points to distinguish what is supposed to be nor-

mal from dysfunction [13,15]. Similar to diagnostic tests in general, it was proposed to use the 0.5- and 2.5-percentile cut-off points, which agreed with an IELT of less than 1 and 1.5 minutes, respectively [13]. In other words, complete agreement was obtained between men with complaints who were actively seeking medical treatment and the fact that they showed a medical ejaculatory dysfunction as formulated in the general male population [10,13]. Based on this agreement, Waldinger et al. proposed lifelong PE as an ejaculatory dysfunction in case of a quantitatively measured IELT below 1–1.5 and perhaps 2 minutes [13]. Moreover, it was proposed to define "lifelong" PE as a neurobiological dysfunction with an unacceptable increase of risk of developing sexual and psychological problems at any time during life in case of IELTs less than 1–1.5 minutes [13]. In addition, it was proposed that all men with an IELT of less than 1 minute (belonging to the 0.5 percentile) have "definite" PE, while men with IELTs between 1 and 1.5 minutes (between 0.5 and 2.5 percentiles) have "probable" PE, indicating that the chance to suffer from PE is higher in case of IELTs less than 1 minute [13]. Moreover, the severity of PE (nonsymptomatic, mild, moderate, and severe) was proposed to be defined in terms of associated psychological problems [13]. One of the advantages of this definition is the medically evidence-based way in which a cut-off level of IELT, i.e., at the 0.5 and 2.5 percentiles, has been established. Although additional epidemiological stopwatch studies in other parts of the world are necessary, it appears that, at this moment, IELT values of 1–1.5 and perhaps 2 minutes come into the nearest direction of both percentiles. Another advantage of the definition is the inclusion of a quantitative biological measure, i.e., the IELT, as well as the inclusion of qualitative psychological measures, i.e., amount of distress and other psychological parameters, which determine the "severity" of PE but not the "diagnosis" of PE [13].

For a good understanding of the 0.5 and 2.5 percentiles to distinguish normal and abnormal IELT values in the general male population, it should be emphasized that the application of these percentiles is only methodologically justified in a genuine "random" nonselected population. In other words, any survey of the IELT in a cohort of men who were selected by inclusion (e.g., by the DSM-IV-TR definition) and exclusion criteria (e.g., erectile dysfunction, specific medications, specific mental or physical disorders) is not suitable for establishing standard reference values by application of these percentiles.

For a DSM definition of PE, however, just focusing on IELT outcomes and epidemiologically determined risk assessment would not be sufficient. An appropriate DSM definition must also include well-defined clusters of symptoms that form the components of a complex PE syndrome.

#### Complaint, Symptom, Dysfunction, and Syndrome

Many "complaints" are based on the "symptoms" of one or more dysfunctions. These dysfunctions are often objective and reproducible. However, there are also "complaints" and "symptoms" without findable objective and reproducible physiological substrates. For example, a man with complaints about rapid ejaculation and a proved short IELT suffers from a "symptom" with an objective and reproducible dysfunction i.e., a short IELT. In contrast, an individual with a similar complaint but with an IELT of more than 10 minutes suffers from aberrant feelings about his ejaculatory performance. This subjective "experience" is his "complaint," and at the same time "symptom" of psychological distress, but this time without an objective and reproducible substrate, i.e., an abnormal IELT.

A "syndrome" is characterized by a "cluster of symptoms," either based on objective and reproducible physiological substrates or without such findable biological phenomena. For example, the syndrome of a major depression consists of the following objective reproducible symptoms: depressed mood most of the day, markedly diminished interest, significant weight loss, insomnia, and concentration problems. In contrast, chronic atypical complaints, such as pain and fatigue, are often "symptoms" of psychological distress but this time often without any findable objective and reproducible dysfunctions.

In fact, complaint, symptom, dysfunction, and syndrome are constructed as a pyramid, with syndrome at the top and complaints at the bottom of the cascade of events. A syndrome consists of a cluster of symptoms, sometimes based on a number of dysfunctions and sometimes not, but always leading to several complaints, regardless of objective and reproducible dysfunctions that are to be found. Objective and reproducible dysfunctions can be treated based on the outcomes of evidence-based medical interventions, whereas no evidence-based treatments are available for symptoms without objective and reproducible substrates. In

such circumstances, treatments remain still necessary but rely frequently on personal experiences and opinions given by authorities and anecdotal evidence. For example, a man who complains about a rapid ejaculation but with an IELT of 10 minutes and with a partner who is not annoyed by his performance, may benefit from psychotherapy, whether or not this can affect his IELT. His personally experienced ejaculatory dysfunction obviously appears to be different from the "PE syndrome," which consists of objective and reproducible short IELTs which "dysfunction" gives rise to a cluster of complaints. In summary, although we recognize syndromes based on nonfindable objective and reproducible dysfunctions that lead to complaints, we would assign the syndrome of PE to those complaints that are based on abnormally short IELTs. The question remains what is normal and what is abnormal. A multinational epidemiological study has clearly shown that the IELT among men behaves according to a naturally distributed pattern and that the use of the 0.5 and 2.5 percentile provides information to be used in future definition of PE in the pending DSM-V edition [12,13].

#### PE as a Complaint

Variability of ejaculatory time is a common phenomenon among men and may become exaggerated after abstaining from sex for a long time, or during hyperarousal and nonpleasurable or pleasurable stress, for example, when having sex with a new partner. A "simple" PE "complaint" needs, therefore, careful exploration, as it may be due to surrounding-related bias rather than evident medical pathology. If early ejaculation does occur at nearly every intercourse, and with nearly every sexual partner, from the first sexual encounters on, the consistency of *complaints* suggests a "medical dysfunction" i.e., *lifelong premature ejaculation* [16]. Similarly, if early ejaculatory complaints occur at every intercourse but nearly always with the same sexual partner, but clearly not from the first sexual encounters on, these PE complaints are also due to a "medical" or "psychological" dysfunction but suggest this time "*acquired premature ejaculation*" [16].

In summary, PE should be regarded as an *ejaculatory complaint* caused by a normal or pathological ejaculatory performance, the latter of which may be due to a dysfunction such as lifelong (medical dysfunction) or acquired PE (medical or psychological dysfunction).

#### The Introduction of PE as a Syndrome

Traditionally, PE has been described as either a "complaint," "disorder," or "dysfunction." However, the functional classification of its different expressions needs a description or definition in terms of a "syndrome." For the simple reason that such a syndromal approach has not been used in the DSM, no operationalization of different syndromes of PE has been described. A syndrome is a cluster of consistent symptoms. PE without these consistent symptoms does not belong to the syndrome of PE, but should be regarded as the "complaint" of an individual who believes or feels that his ejaculation time is too short, or actually but irregularly has an objective short IELT. By introducing PE as a syndrome, we can distinguish two types, the already accepted Lifelong and Acquired types. We propose a third type of PE to be called "Natural Variable PE," which is not a syndrome but a cluster of inconsistent symptoms of rapid ejaculation.

#### PE as a Syndrome

Premature ejaculation in the context of a clinical entity or a syndrome has for the first time been described by Bernard Schapiro in 1943 [17]. He distinguished Types A and B that were later termed "lifelong and acquired" by Gospodinoff [18]. However, in order to make a clear distinction between PE as a description of a normal phenomenon or as a symptom of a medical or psychological dysfunction (i.e., lifelong or acquired PE), we propose the introduction of a third form of PE termed "Natural Variable PE" as its logical consequence. In the last form, PE may be perceived as a normally occurring phenomenon and sometimes an ejaculatory complaint. This view appears to be reasonable in the light of high PE prevalences of 20–40% in population surveys in which large cohorts of men were questioned by telephone, Internet, or anonymous, mailed questionnaires [19–22].

#### The Syndrome of Lifelong PE

Research of recent years provided accumulating evidence to state that lifelong PE is characterized by a cluster of objective and reproducible symptoms and thus should be regarded as a syndrome [14,16,23,24]: (i) Men have an apparently *consistently* abnormal early ejaculation time in 90% of intercourse; (ii) The problem is there from the

onset of first sexual encounters in puberty or adolescence; (iii) Occurring with all woman sexual partners; (iv) Keeping the same rapidity in 70% during life, while becoming even more rapid in the remaining group; (v) In total, 80% of the complainers ejaculate within 30 seconds (measured with a stopwatch), 10% within 40–60 seconds, and some other 10% within 1–2 minutes; (vi) Early ejaculations occur either during foreplay before penetration, or immediately during penile–vaginal contact (ejaculatio ante portas); (vii) Due to frustration there may be problems among partners. The men themselves may react with low self-esteem and depressive feelings; and (viii) The complaints may also lead to secondary sexual problems, such as coitus anticipation anxiety, coitus avoidance, and decreased sexual desire.

Two other symptoms, which have not been investigated in depth, may be a part of the syndrome of lifelong PE as well. In 1943, Bernard Shapiro noted for the first time that many men with the PE syndrome have rapidly occurring erections, which he called "erectio praecox [17]." This term has never been quoted elsewhere in the literature. Particularly, because erectio praecox indicates that men with lifelong PE do not a priori have erectile dysfunction, Waldinger reintroduced its clinical importance, and hypothesized that erectio praecox in the context of lifelong PE may be associated with increased oxytocin release [11]. Bernard Shapiro also noted that lifelong PE seems to occur more frequently among family members [17]. Indeed, in a cohort study, Waldinger et al. demonstrated that the prevalence of lifelong PE, defined in terms of an IELT of less than 1 minute, in first-degree male family members was higher than could be expected on the basis of chance alone [25].

Based on animal [26–29] and human [12] data, showing a similar natural distribution of the ejaculation time among men and male rats, it is reasonable to speculate about a neurobiological origin of lifelong PE. Moreover, according to the rules of statistics in biology, lifelong PE represents the extreme left of the distribution curve (less than 0.5–2.5 percentile of the population) [13]. This neurobiological aberrant phenomenon may implicate that men who belong to this left extreme display a "fixed" rapid ejaculation time. The question arises whether such a fixed rapidity can be manipulated either by psychotherapy or by drug treatments. Thus far there are only very limited data in the literature in support of favorable effects of psychotherapy [30–32]. Psychotherapeutic data pertain, however, to feelings and subjective experiences and ignore analyses of objective ejaculatory time measurements, typically according to views of Masters and Johnson [33] and the DSM criteria [3,4]. In contrast, a large body of data have been published about drug treatments with clomipramine and SSRIs, which demonstrate a significant delay in ejaculation times [1]. These drug treatment results are also in favor of the neurobiological approach of lifelong PE. The suggested familiar prevalence of lifelong PE being localized at the left side of the natural distribution of the IELT may be associated with genetic vulnerability [25].

#### The Syndrome of Acquired PE

Men with acquired PE have consistent ejaculatory problems that occur gradually or suddenly in later life i.e., after the first normal sexual encounters in puberty or adolescence. In case of ambivalent feelings concerning a particular sexual partner or general relational problems, treatment with counselling or psychotherapy appears to be indicated [34,35]. Another cause of acquired PE is coexisting of urogenital disease like prostatitis or inflammatory conditions requiring urological expertise [36,37]. In contrast to lifelong PE in which the thyroid function is normal [38], a recent study by Carani et al. showed that secondary PE may be caused by the thyroid dysfunction [37]. In contrast to lifelong PE, treatment of the underlying dysfunction in acquired PE, whether somatic or psychological, may lead to its definite cure.

#### Natural Variable PE

Many conceivable situations may lead to inappropriate sexual arousal like abstaining from sex for a long time, being just very sexually excited, having sex with a new partner, with the wrong partner, or with a partner who is not sexually attractive. In these situations, the ejaculation time is never consistently rapid but merely coincidentally and situationally. It is evident therefore that this type of PE should not be regarded as a symptom or manifestation of true pathology but of normal variation in sexual performance. Men with "Natural Variable PE" usually cope very well with their coincidental rapid ejaculation, but in case of seeking advise or information, they need to regain confidence by therapists explaining to them that their complaint relates to situational problems and

reversible factors. Therapists should be cautious not to stigmatize these men or to pathologize their ejaculatory problem.

Prevalence and incidence of "Natural Variable" type of PE are unknown, but it may be that the existence of this type contributes to the high prevalence data of PE that have been found in various surveys [19–22]. The high prevalences of men with PE and the low numbers of those who actively seek medical treatment are most probably caused by the confusion of PE as a "complaint" and as a "symptom" of the genuine "syndrome PE." Complaints of rapid ejaculation in the context of "Natural Variable PE" are characterized by the inconsistent occurrence of actually rapid or as abnormally rapid experienced IELTs, and are presumably not severe enough to seek medical treatment. The discrepancy in PE prevalence, i.e., a prevalence of PE "complaints," most often found to be about 20–40% in the general population, and the low rates of men actively seeking medical treatment, should not automatically be interpreted as the result of unawareness or lack of information about existing treatment options. It may also demonstrate our idea that a lot of men with "complaints" of PE belong to the "Natural Variable" type of PE and thus do not need treatment, as their complaints are infrequent or relatively mild enough to withhold them from seeking medical treatment.

There is indirect evidence that men with this third type of PE can cope with their problem because of its situational or temporarily nature. Available epidemiological information has thus far focused on PE as a "complaint" and not as a well-circumscribed "syndrome." Most studies report about "complaints" expressed for the duration of 6–12 months, thereby ignoring the issue of *lifelong* PE. Rapid ejaculations may occur to many men, and it is really not surprising that these men report an occasionally too rapid ejaculation in epidemiological studies. However, this does not mean that all of them have the consistent symptoms of the "syndrome" of *lifelong* PE. An illustration of this clinically relevant issue can be derived from a study by Fugl-Meyer and Fugl-Meyer [39,40]. In this Swedish survey, 1,256 men and 1,099 women, aged 18–74 years, who were not a couple but had been sexually active in the past 12 months, were questioned whether they had noticed PE during 12 months prior to the interview. The prevalences of men who responded that PE occurred "always" and "nearly always" were 0.5% in both response categories, with similar responses in women ("always" in 0.4% and "nearly always" in 0.9%) [39,40]. Prevalences for "rather often" were 7–6% in men and women, respectively, while for the male response categories "rather rarely" and "hardly ever," the prevalences were 17–27%, and 15–27% for the woman partners [39,40]. In the response category "never," it was 48% of men and 51% of women. These data showed that PE occurred "always" or "nearly always" in 1%, which is in line with a consistent pattern of complaints as also noticed in men with lifelong and/or acquired PE syndromes [10]. Similarly, it occurred "rather often" in 7%, which may also be in line with those individuals with lifelong and/or acquired PE syndromes. Based on this study, it can be speculated that, according to the consistent nature of the complaints, lifelong PE is prevalent in some 1–8% of men.

To summarize, 8% are consistent complainers, while 17% complains rather rarely, and 27% hardly ever. Complainers are therefore prevalent in 52% of a Swedish male cohort, of whom 8% expressed complaints of consistent rapid ejaculations, while the remainder 44% are supposed to belong to the proposed group of men with the "Natural Variable" type of PE.

#### PE Syndromes Categorized as DSM–Axis I Disorder

There is no strong evidence for a psychological cause of lifelong PE, but in "Acquired" and "Natural Variable" types, a psychological cause can not be excluded. However, is it scientifically correct to state that PE in general is a "mental" disorder as is assumed in the consecutive DSM editions and in the ICD-10? Karl Abraham (in 1917) was the first to call it a mental or psychological disorder, for which psychotherapy is needed [41]. However, neither a neurobiological basis nor a distinction between lifelong and acquired PE was known at that time. PE remained without somatic or psychological vignette until 1980, when the DSM committee of the American Psychiatric Association decided that it should be regarded as a mental disorder as became officially stated in the DSM-III classification system [42]. PE was classified as an Axis I diagnosis, similar as major depression or any other anxiety disorder. Axis III diagnoses were particularly meant for physical disorders. However, the Axis I classification may erroneously lead to the conclusion that lifelong PE is a mental disorder in the classical psychological sense. It should be noted, however, that in line with current neuropsychiatric developments,

the term "mental disorder" has undergone important changes in recent years. For example, the DSM-IV-TR states that the distinction between a mental disorder and a general medical condition is merely as one of convenience and should not imply that mental disorders are unrelated to physical or biological factors (DSM-IV-TR, p. xxxv) [3].

#### Control on Ejaculation and PE Definition

In part I of this article, we described how Masters and Johnson originally used "control" as the ability to delay ejaculation until the woman partner becomes satisfied [33]. However, today's vision is that "control" pertains to the ability to withhold ejaculation at the moment of imminent ejaculation. This does not mean that the inability to withhold ejaculation at its most imminent moment would mean that one would automatically suffer from PE. The ability of "control" over ejaculation is most probably a "neuropsychological" function that is subjectively experienced, whereas the ejaculatory process is merely a "physical" function that can be numerically quantified. Moreover, subjective "feelings" and "experiences" of control follow different neuronal circuits in the central nervous system than those involved in the motoric "capacity" to control imminent ejaculation. There are indications that the ability to control imminent ejaculation is mediated by the frontal lobe of the cerebral cortex. For example, in a positron emission tomography (PET)-scan study of 11 healthy male volunteers, unsuccessful attempts to ejaculate showed activation in the right orbitofrontal cortex, the left dorsal prefrontal cortex, and bilaterally in the anterior insula [43]. The inability to control ejaculation is presumably associated with frontal disinhibition of lumbosacral neuronal processes [44,45]. As the daily use of SSRIs often (but not always) contributes to an increased feeling of control to withhold imminent ejaculation, it may be postulated that the experience of control is at least partly mediated by central serotonergic (5-hydroxytryptamine) neurotransmission [46]. On the other hand, there are mounting animal data to suggest that ejaculation is mediated by the temporal and parietal lobe in conjunction with the hypothalamus, brain stem, and spinal cord [28]. Tactile sensoric information from the glans penis is perceived in the temporal and parietal areas of the cerebral cortex while the motoric output runs through the brain stem. However, our neurobiological knowledge, particularly of the human brain involved in ejaculation, is still rudimentary.

Clinical studies have been conducted to link "feelings of control" to "the ejaculation time." For example, in a sample of 57 men, Grenier and Byers [47] found a significant but only a moderate correlation between experienced ejaculatory control and self-perceived duration of the IELT ($r = 0.31$, $P < 0.005$). Similarly, in the aforementioned study by Waldinger et al., 62% of men with lifelong PE reported a lack of control, and another 24% a moderate control [10]. In other words, men with genuine lifelong PE do not necessarily complain about "lack of control," while the opposite holds true for men with normal IELT values but who still complain about "lack of control." Possibly, these individuals express their difficulties to withhold ejaculation as "lack of control," independent of the duration of their ejaculation time, as soon as ejaculation becomes imminent. When such an event of lack of control should be regarded as normal or pathological remains thus far an open question.

In order to explain the spectrum of possible combinations between the IELT and the ability to control ejaculation, we distinguish four combinations (Figure 1): men with PE, represented by men with a short IELT, and men with non-PE represented by normal IELT values; both men with PE and non-PE can be subdivided into two groups, one with normal control and the other without control. Of those four groups, there is only one group represented by a short IELT and "no Control" (Figure 1, solid square). In summary, the weak to moderate correlation between a short IELT and feelings of "lack of Control" can be explained by the variety of group combinations. Any new definition of PE should be based, therefore, on population-based cut-off points that are obtained from randomly nonselected male cohorts, thereby minimizing the risk to pathologize men with normal IELT values and feelings of "lack of Control" at the moment of imminent ejaculation.

#### Pharmaceutical Interest in PE Definition

Pharmaceutical companies are obviously keen to start campaigns to encourage the use of drugs against PE in as many men as possible. It is thinkable that such strategies are aimed to evoke the interest of men with "Natural Variable" PE to use drugs against PE. An attractive approach for any pharmaceutical company is to emphasize, for

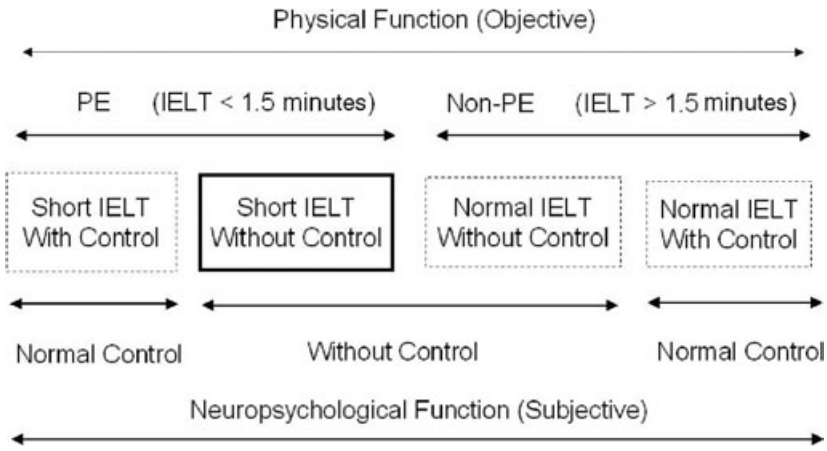


**Figure 1** Four combinations of the intravaginal ejaculation latency time (IELT) and feelings of control. The moderate relationship between "short IELT" and "without control" is explained by the limited overlap of both functions, represented by the solid square. PE = premature ejaculation.

example in press releases, that PE is the most frequent sexual "dysfunction," or in DSM terms "male sexual disorder," thereby referring to the very high prevalence rates that were published in the range of 20–40%. However, the reported high prevalence rates pertained to "complaints" of PE assessed through questionnaires. It is of note that complaints are not identical to a PE "syndrome," "disorder" of "dysfunction." Moreover, according to our interpretation of the data of the study of Fugl-Meyer and Fugl-Meyer [39,40], there is (indirect) evidence that the prevalence of the real "PE syndromes" or "PE dysfunctions" is much lower (1–8%). Based on the data from a genuine random European and U.S. survey [12,13], it may even be lower (2.5%). These discrepancies of what has been published in terms of "complaints" and that of genuine PE syndromes are clearly striking and certainly not attractive for impressive marketing incentives. From the medical point of view and, thus, based on strong evidence, drugs should be prescribed only to men with the genuine PE syndromes, i.e., the men with lifelong and acquired PE. However, as it is inevitable that the potential "consumer market" for PE drugs will consist of a large part of men with "Natural Variable PE," it is conceivable that pharmaceutical companies may disregard the statistical cut-off points of the 0.5 and 2.5 percentile, i.e., an IELT of less than 1–1.5 minutes. For example, companies may try to get higher cut-off points than 1–1.5 minutes by using the 0.5- and 2.5-percentile IELT values from nonrandomly selected cohorts. They may also include as many men as possible, meaning also men with "Natural Variable PE," by promoting the diagnosis of PE in terms of "Lack of Control" and emphasizing the clinical importance of PROs, which usually also include "Lack of Control." As both men with PE (i.e., IELT less than 1.5 minutes) and non-PE (i.e., IELT more than 1.5 minutes) may complain of "lack of control" and a qualitative cut-off point of "control" vs. "lack of control" is difficult to make, such a definition of PE is certainly favorable for pharmaceutical marketing strategies. In other words, if we decide to choose for the "lack of control" definition, i.e., a definition without a cut-off point for the IELT, it means that we accept that drugs against PE become promoted on a large scale to men with "Natural Variable PE."

#### Implementation of the IELT into the Definition of PE

Recent data about PE originate from a large epidemiological survey of IELT in men, showing that the IELT is naturally and skewed distributed among men [12]. In addition, daily treatment with serotonergic antidepressants, such as clomipramine, paroxetine, sertraline, and fluoxetine, has repeatedly demonstrated to clinically significantly delay ejaculation [1].

As previously stated, the DSM definition of PE needs a thorough update that should be based on recent outcomes of epidemiological studies and randomized clinical trials. Extension of the current categorization into two distinct PE syndromes (Lifelong PE and Acquired PE) and into Natural Variable PE is highly recommended. An addition of the IELT into the DSM definition of PE is supported by statistical data about the IELT in the healthy male population in which any rapid ejaculatory dysfunction has been defined as an IELT below the 2.5-percentile cut-off point [13]. Positive associations have been shown between a short IELT and complaints about ejaculatory performance. It is therefore assumed to consider the

IELT as a risk factor to predict complaints of a rapid ejaculatory performance, similar as bone mineral density or cholesterol for osteoporotic fractures and myocardial infarction [13]. However, in contrast to the latter well-known risk factors, it is not reasonable to screen large populations on the IELT for the selection of men who need treatment for PE, as PE is not a life-threatening disease. It is more rational to prescribe drugs against PE to anyone who complains of a genuinely short IELT, which is scientifically based on reference values obtained from the general male population. It is also evident that any complainers with a normal IELT need a careful diagnostic work-up to optimize the treatment of choice like several forms of psychotherapy or medical interventions for urogenital disorders.

#### Epidemiological Research

Epidemiological studies have always investigated the prevalence of PE as a "complaint" and not as a "syndrome." Additional information is needed, and future research should therefore focus on the investigation of the prevalence of the so-called PE syndromes "Lifelong" and "Acquired PE" but also on that of the prevalence of "Natural Variable PE." An operational definition in the DSM definition of PE of "the three categories" has important clinical consequences with regard to treatment. For example, it may well be that behavioral psychotherapy appears beneficial in those men complaining of "Natural Variable PE," but not in men with Lifelong PE. It could also be that the incidence of SSRI-induced side effects is different in men with "Normal Variable PE" as compared with those with "Lifelong PE." For example, it is speculated that SSRI-induced erectile difficulties become less clinically relevant in some men with lifelong PE as they are naturally "protected" by quick occurring erections (erectio praecox).

#### Proposal for DSM-V and ICD-11 Classification of PE

In contrast to the current DSM definition, we propose three separate operationalized definitions of PE for the DSM-V and ICD-11 according to the three types of PE (see Addendum). These three definitions are devoid of multi-interpretable terms accepting that a PE "complaint" can be expressed as "having ejaculations that occur too rapidly" or as "having insufficient or lack of control." All proposed definitions include a quantification of the ejaculation time (IELT). The cut-off point of the IELT of 1.5 minutes in lifelong PE is an acceptable upper limit based on several controlled clinical trials using a stopwatch [10,12]. However, it should be noted that the majority of men actively seeking treatment for lifelong PE usually ejaculate within 1 minute [10]. With regard to the proposed 1.5-minute cut-off point, one must realize that men with consistent IELTs below 1 minute are more at risk to develop psychological problems at any point during life [13].

The issue of quantifying the ejaculation time needs further explanation. It has been shown that men in general are bad estimators of their own ejaculation time. For example, in a meta-analysis of 35 SSRI studies on PE comparing stopwatch-assessed IELTs and spontaneous reports on IELTs, it appeared that the variability of the spontaneous reports and questionnaire answers was statistically significantly higher compared with real-time stopwatch assessment, indicating the inability of the participants to assess time accurately in case of IELT values higher than 1–1.5 minutes [1]. However, men who are used to IELTs of less than 1 minute appear to be more accurate to assess their IELTs. For example, in a study among 110 men with lifelong PE, memorized IELTs were compared using either spontaneous reports or answers on a questionnaire with prospectively collected real-time stopwatch data at each intercourse during 4 weeks [10]. The majority of men estimated their IELT to be less than 1 minute, with an initial overestimation both by spontaneous report ($r = 0.56$, $P < 0.001$; mean difference $13 \pm 32$ seconds) and questionnaire ($r = 0.59$, $P < 0.001$; mean difference $12 \pm 31$ seconds). An even greater overestimate was observed in the woman partners ($r = 0.20$, $P < 0.001$; mean difference $38 \pm 72$ seconds; and $r = 0.23$, $P < 0.001$; mean difference $27 \pm 69$ seconds, respectively). These data demonstrate that self-reports are clearly inferior as compared with prospective real-time assessments of the IELT. The correlations between men and their woman partners with respect to self-reported IELT and IELT duration reported on a questionnaire were also weak ($r = 0.20$, $P < 0.001$ and $r = 0.16$, $P < 0.025$, respectively) [10].

The erroneous self-reported estimates differed about 10–30 seconds from the real-time measurements and are therefore inappropriate for scientific use. However, self-reported estimates showed a median time of 20 seconds with an intraclass

variation coefficient of 0.71, meaning that the IELTs were relatively constant over the 4-week period of assessment. These findings enable the use of self-reported IELTs in men who complain about a too rapid ejaculatory performance at least within 1 minute and who require medical treatment outside scientific protocols. In other words, by asking "what do you mean with rapid?", a high number of men with actual IELTs of less than 1 minute will stick to a reasonable estimate. In case of a reply like "mostly within 30 seconds or within 1 minute," one can be quite confident that the prospective real-time assessed IELT will be below 1 minute. Such a moderate correlation between spontaneous report and stopwatch-assessed IELT has also been found in a smaller group of men [48]. However, in case of a reply like "within 4–5 minutes," prospective real-time assessment remains crucial.

In contrast to Lifelong PE, a precise IELT cut-off point for Acquired PE has been insufficiently investigated. To avoid confusion, we formulated a 1.5-minute cut-off point for Acquired PE, but further studies are needed. As mentioned previously, the three types (Lifelong, Acquired, and Natural Variable PE) are characterized by key features, and therefore each definition remains exclusive. As proposed previously, the severity of PE should be described in terms of the degree of psychological distress and relationship problems [13]. Thus in contrast to the current DSM definition, in which "distress" and "interpersonal difficulties" are a prerequisite for the diagnosis, in the new proposal (see Addendum) both features are not mentioned as prerequisite but as a result of the problem determining the severity of PE.

All three definitions contain two criteria regarding feelings of ejaculatory control, which is operationally defined as the ability to withhold ejaculation at the moment of imminent ejaculation. As there is a wide range of subjective feelings concerning "control," and a cut-off point in this qualitative variable is difficult to establish, the item of "lack of Control" has been made dependent on the IELT cut-off point of 1.5 minutes.

It should be noted that all research made on PE has been focused on heterosexual men and their woman partners. The formulation of the definitions is therefore based on heterosexual couples. Although we assume that the proposed definitions may also pertain to homosexual men, there is no strong evidence for such a statement. Stopwatch studies and clinical trials with drugs are, therefore, also needed in homosexual couples.

## Conclusion

Due to its low positive predictive value, the current DSM-IV-TR definition is inappropriate for clinical, epidemiological, and drug treatment trials of PE. Revision of the DSM definition of PE is therefore greatly encouraged.

In this article, we delineated the differences between complaint, symptom, dysfunction, and syndrome—which is thus far not in line with the current DSM definition of PE, in which PE is only mentioned as a "complaint." However, defining PE as a syndrome would be far more beneficial for practical use as well as for research.

For an evidence-based definition of PE, it is important to distinguish the two typical PE syndromes: Lifelong and Acquired PE. We proposed "Natural Variable PE" as a third type of PE. In this category, ejaculatory complaints are only transient and belong to the normal variation of ejaculatory performance. Their occurrence is not necessarily based on medical or psychological pathology. In addition, we formulated operationalized definitions of both Lifelong, Acquired, and Natural Variable PE for the pending DSM-V and ICD-11. The definitions consist of key features, contain a cut-off point of the IELT of 1.5 minutes, and include feelings of control defined as the ability to withhold ejaculation at the moment of imminent ejaculation. Moreover, the severity is expressed by different degrees of distress and interpersonal difficulties. In this way, we integrated neurobiological, neuropsychological, and psychological factors into the three definitions of PE.

Although the definitions of Lifelong, Acquired, and Natural Variable PE are supported by epidemiological and clinical data, more research, particularly in the field of Acquired and Natural Variable PE, remains essential. The introduction of the duration of the IELT into the definitions means that robust statistical evidence becomes acknowledged as one of the mainstays for establishing the diagnosis PE. We are convinced that these new definitions will form a better framework for clinicians to diagnose Lifelong, Acquired, and Natural Variable PE. Moreover, the definitions are made in such a way that pharmaceutical company-driven marketing campaigns can not pathologize men with "Natural Variable PE." As it probably will take another 5 years before the DSM-V and ICD-11 will be published, research of PE should abandon the current DSM-IV-TR and ICD-10 definitions. We hope that future clinical, epidemiological, and drug treatment studies of PE will use

aforementioned definitions to get a clearer view on PE.

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*Conflict of Interest:* None.

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## Addendum Part II

### *Proposal for DSM-V Definition of Premature Ejaculation*

#### Lifelong Premature Ejaculation

Diagnostic criteria

A Consistent involuntary rapid ejaculation during intercourse (i.e., an ejaculation that occurs within 1.5 minutes after vaginal penetration)
B Early ejaculations occur in 90% or more cases of intercourse
C Early ejaculations occur with nearly every woman partner
D Early ejaculations exist since or around the first sexual encounters
E The rapidity of ejaculation remains similar throughout life or may become more rapid with aging
F In absence of underlying pathology, erectile function is normal but may also occur quite rapidly (erectio praecox)
G Ability to control ejaculation (i.e., to withhold ejaculation at the moment of imminent ejaculation) may be diminished or lacking, but is not obligatory for the diagnosis
H Consistent experiences of diminished or lacking of control of ejaculation should go along with a short ejaculation time (i.e., an ejaculation that occurs within 1.5 minutes after vaginal penetration)
I The ejaculation rapidity is not due exclusively to the direct physiological effect of any sub-

stance use or medical condition (e.g., endocrine or urological disorders)

Code as follows:

X.a With distress (mild, moderate, severe)
X.b Without distress
Y.a With relationship problems (mild, moderate, severe)
Y.b Without relationship problems

*Acquired Premature Ejaculation*

Diagnostic criteria

A Consistent or inconsistent involuntary rapid ejaculation during intercourse (i.e., an ejaculation that occurs within 1.5 minutes after vaginal penetration)
B Early ejaculations may occur with only one particular partner or with nearly every woman partner
C Early ejaculations have started at a certain moment in life before which the person never experienced problems with early ejaculations
D After its onset, the rapidity remained similar or aggravated throughout life
E Ability to control ejaculation (i.e., to withhold ejaculation at the moment of imminent ejaculation) may be diminished or lacking, but is not obligatory for the diagnosis
F Consistent or inconsistent experiences of diminished or lacking of control of ejaculation should go along with a short ejaculation time (i.e., an ejaculation that occurs within 1.5 minutes after vaginal penetration)
G The ejaculation rapidity is either due to the direct physiological effect of any substance or medical condition (e.g., endocrine or urological disorders) or due to psychological and/or interrelationship problems

Code as follows:

X.a With distress (mild, moderate, severe)
X.b Without distress
Y.a With relationship problems (mild, moderate, severe)
Y.b Without relationship problems

*Natural Variable Premature Ejaculation*

Diagnostic criteria

A Inconsistent involuntary rapid ejaculation during intercourse (i.e., an ejaculation that occurs in less than or more than 1.5 minutes after vaginal penetration)
B Early ejaculations occur irregularly during intercourse
C In most cases of intercourse ejaculatory performance is not rapid or perceived as rapid
D Ability to control ejaculation (i.e., to withhold ejaculation at the moment of imminent ejaculation) may be diminished or lacking, but is not obligatory for the diagnosis
E Experiences of diminished or lacking of control of ejaculation, whether consistent or inconsistent, go along with either a short or normal ejaculation time (i.e., an ejaculation that occurs in less than or more than 1.5 minutes after vaginal penetration)
F The ejaculation rapidity is not due exclusively to the direct physiological effect of any substance use or medical condition (e.g., endocrine or urological disorders)

Code as follows:

X.a With distress (mild, moderate, severe)
X.b Without distress
Y.a With relationship problems (mild, moderate, severe)
Y.b Without relationship problems