ABSTRACT

Introduction. The medical literature contains several definitions of premature ejaculation (PE). The most commonly quoted definition, the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders-Fourth Edition-Text Revision, and other definitions of PE are all authority based rather than evidence based, and have no support from controlled clinical and/or epidemiological studies.

Aim. The aim of this article is to develop a contemporary, evidence-based definition of PE.

Methods. In August 2007, the International Society for Sexual Medicine (ISSM) appointed several international experts in PE to an Ad Hoc Committee for the Definition of Premature Ejaculation. The committee met in Amsterdam in October 2007 to evaluate the strengths and weaknesses of current definitions of PE, to critique the evidence in support of the constructs of ejaculatory latency, ejaculatory control, sexual satisfaction, and personal/interpersonal distress, and to propose a new evidence-based definition of PE.

Results. The committee unanimously agreed that the constructs that are necessary to define PE are rapidity of ejaculation, perceived self-efficacy and control, and negative personal consequences from PE. The committee proposed that lifelong PE be defined as "...a male sexual dysfunction characterized by ejaculation which always or nearly always occurs prior to or within about one minute of vaginal penetration, and the inability to delay ejaculation on all or nearly all vaginal penetrations, and negative personal consequences, such as distress, bother, frustration and/or the avoidance of sexual intimacy." This definition is limited to men with lifelong PE who engage in vaginal intercourse. The panel concluded that there are insufficient published objective data to propose an evidence-based definition of acquired PE.

Conclusion. The ISSM definition of lifelong PE represents the first evidence-based definition of PE. This definition will hopefully lead to the development of new tools and Patient Reported Outcome measures for diagnosing and assessing the efficacy of treatment interventions and encourage ongoing research into the true prevalence of this disorder and the efficacy of new pharmacological and psychological treatments.

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Introduction

The premise that premature ejaculation (PE) is a psychosomatic disturbance was first suggested by Schapiro in 1943 [1]. For many years, behavioral psychotherapy was the cornerstone of treatment and included techniques such as the stop–start method with or without the squeeze technique [2,3]. The on-demand use of topical anesthetic cream to delay ejaculation was first described in the 1930s and is regarded as the oldest drug treatment of PE [1]. Over the past 20–30 years, the PE treatment paradigm has expanded to include drug treatment. During the 1970s and 1980s, double-blind, placebo controlled studies demonstrated the efficacy of clomipramine, the most serotonergic tricyclic antidepressant in delaying ejaculation [4,5]. Subsequent animal and human sexual psychopharmacological studies have demonstrated that serotonin and 5-HT receptors are involved in ejaculation and confirm a role for selective serotonin reuptake inhibitors (SSRIs) in the treatment of PE [6–12]. Over the past 15 years, an increasing number of well-controlled, evidence-based studies have demonstrated the efficacy and safety of SSRIs in delaying ejaculation, confirming their role as first-line agents for the treatment of lifelong and acquired PE [13]. More recently, there has been increased attention to the psychosocial consequences of PE, its epidemiology, its etiology, and its pathophysiology by both clinicians and the pharmaceutical industry [14–19]. The pharmaceutical industry has contributed to our current understanding of PE over the past 2–3 years. Most of the recent large PE observational studies have been designed and conducted, with data analyzed, interpreted, and reported by industry employees and industry-sponsored investigators. Continued industry participation in evidence-based PE research is encouraged as it is likely to benefit the common interest of encouraging effective and responsible use of investigational and existing drugs, improved treatment adherence, and improved patient outcomes [20].

The population of men with PE is not homogeneous. In 1943, Schapiro classified PE as either primary (lifelong) or secondary (acquired) [1]. Recently, Waldinger et al. expanded this classification to include lifelong PE, acquired PE, natural variable PE, and premature-like ejaculatory dysfunction [21]. Lifelong PE is a syndrome characterized by a cluster of core symptoms including early ejaculation at nearly every intercourse within 30–60 seconds in the majority of cases (80%) or between 1 and 2 minutes (20%), with every or nearly every sexual partner and from the first sexual encounters onward. Acquired PE differs in that sufferers develop early ejaculation at some point in their life, having previously had normal ejaculation experiences. Acquired PE may be because of psychological or relationship problems, erectile dysfunction (ED), prostatitis or thyroid dysfunction [22–25]. In natural variable PE the ejaculation time is never consistently rapid but merely coincidental and situational. This type of PE should be regarded as a normal variation in sexual performance and is characterized by inconsistent and irregular early ejaculation, often with reduced ejaculatory control [26]. Men with premature-like ejaculatory dysfunction complain of PE but have a normal ejaculatory latency of 3–6 minutes. It is characterized by a preoccupation with a subjective but false perception of PE with an ejaculatory latency within the normal range but often with reduced ejaculatory control.

Research into the treatment and epidemiology of PE is heavily dependent on how PE is defined. The medical literature contains several univariate and multivariate operational definitions of PE [3,27–34]. Each of these definitions characterize men with PE using all or most of the accepted dimensions of this condition: ejaculatory latency, perceived ability to control ejaculation, reduced sexual satisfaction, personal distress, partner distress, and interpersonal or relationship distress. Although the most commonly quoted definition, that of the Diagnostic and Statistical Manual of Mental Disorders-Fourth Edition-Text Revision
(DSM-IV-TR), and other definitions of PE differ substantially, they are all authority based, i.e., expert opinion without explicit critical appraisal [35], rather than evidence based and have no support from controlled clinical and/or epidemiological studies. Additionally, these definitions are primarily conceptual in nature, are vague in terms of operational specificity, and rely on the subjective interpretation of the concepts by the clinician. This lack of agreement as to what constitutes PE continues to hamper clinical research into the etiology and management of this condition, and the development of Patient Reported Outcomes (PROs) to diagnose and assess treatment intervention strategies [36].

In August 2007, the International Society for Sexual Medicine (ISSM) appointed several international experts in PE to an Ad Hoc Committee for the Definition of Premature Ejaculation and convened a meeting in Amsterdam in October 2007 for the purpose of developing a contemporary, evidence-based definition of PE. The concept of evidence-based medicine was interpreted by the committee as the integration of individual clinical expertise with the best available external clinical evidence from systematic research [37]. The meeting was supported by unrestricted research grants from Plethora Solutions and Johnson and Johnson. However, the ISSM required complete independence from industry during the development of the new definition of PE. There were no industry representatives at the meeting and there was no attempt by industry to influence any part of the development process at any time. The committee was chosen by peer recommendation from 10 experts and opinion leaders in sexual medicine, each of whom was asked to nominate, based on expertise in PE, 10 candidates. Thirty-five names were suggested by at least one peer; 22 of the 35 were nominated by two peers or more; 12 names were nominated by three peers or more and a few names were nominated eight times. Several additional experts in sexual medicine, including three women, were invited despite not being nominated in order to provide a balance of opinion, knowledge, gender, and geography. Ultimately, 26 experts were invited to the meeting and 21 attended. These 21 included several of the world’s most highly recognized experts on PE and included eight psychologists or psychiatrists, seven urologists, one sexual health physician, one primary care physician, one neuro-urology researcher, one clinical pharmacologist, one endocrinologist, and one radiation oncologist. All of the attendees were ISSM members. The meeting was organized by the current ISSM president Ira Sharlip, chaired by the ISSM Standards Committee chairman Hartmut Porst, and facilitated by the ISSM president-elect John Dean.

This article chronicles the development of current definitions of PE and details their strengths and weaknesses, critiques the evidence in support of the constructs of ejaculatory latency, ejaculatory control, sexual satisfaction, and personal/interpersonal distress, and proposes a new definition of PE.

Operationalizing PE Variables and Constructs

A construct is a nonobservable, latent variable that is presumed to exist, is an attribute of people, and is used to help explain or predict variation in responses or behavior [38]. In the study of PE, rapidity of ejaculation, perceived ejaculatory self-efficacy or control, and negative personal and interpersonal consequences (e.g., distress) represent constructs that require operationalization. Operationalization is the process of defining a construct or variable by the development of a measure, procedure, or operation for the identification of instances of that construct or variable.

Operationalization and the careful determination of cutoffs for each variable will minimize but never completely eliminate inclusion (false positive) or exclusion errors (false negative) of PE classification of those who have PE vs. those who do not. More restrictive criteria are more likely to result in errors of exclusion whereas more lenient criteria may result in errors of inclusion. Determination of cutoff values for variables must include careful consideration of the significance and impact of the resulting classification errors on the diagnosis of PE. The use of a multivariate approach to defining and diagnosing PE will minimize these errors of classification.

The constructs of PE are difficult to define and operationalize. They can be operationalized using a variety of measures and no single operational measure will completely and precisely capture the essence of each construct [39]. For example, rapidity of ejaculation can be operationalized using estimation of ejaculation latency, stopwatch measurement of ejaculation latency or thrust counting by either the man or his partner. Similarly, perceived ejaculatory self-efficacy and ejaculatory control can be operationalized by measurement of improvements in ejaculation latency time during attempts to delay ejaculation.
using self-estimation or stopwatch measurements or the calculation of the relative fold-increase in ejaculatory latency, or by the measurement of the subjective feeling of ejaculatory control using validated single or multi-item multi-domain PE inventories. And finally, the negative personal and interpersonal consequences of PE can be operationalized by measurement of sexual or global levels of distress, bother, frustration, anxiety, depression, confidence, self-esteem and quality of life, and sexual satisfaction for both men and their partners using validated single or multi-item multi-domain PE inventories, omnibus sexual inventories, quality-of-life and relationship-quality inventories. Other concerns with operationalizing distress and bother relate to the quality of the PRO employed and its psychometric characteristics.

Furthermore, the measures of rapidity of ejaculation, perceived self-efficacy and control, and negative personal and interpersonal consequences are interrelated and may be confounded by each other and by multiple other variables. These variables include the overall physical and psychological health of the man and his partner, the frequency of sexual intercourse, the period of time elapsed since the previous ejaculation, the duration and content of foreplay, the sexual position, the depth, force, and frequency of penile thrusting, the partner’s pelvic floor muscle tone, and the extent of partner vaginal lubrication. Clearly, the process of PE construct operationalization will ultimately determine who is diagnosed with PE as well as the types and consequences of errors that result from implementation of the diagnostic procedure [39].

The ISSM Definition of PE

Members of the ISSM Ad Hoc Committee for the Definition of Premature Ejaculation unanimously agreed that the constructs that are necessary to define PE are time from penetration to ejaculation, inability to delay ejaculation, and negative personal consequences from PE. The ISSM Ad Hoc Committee for the Definition of Premature Ejaculation defines lifelong PE as a male sexual dysfunction characterized by

- ejaculation that always or nearly always occurs prior to or within about one minute of vaginal penetration;
- the inability to delay ejaculation on all or nearly all vaginal penetrations; and
- negative personal consequences such as distress, bother, frustration, and/or the avoidance of sexual intimacy.

The committee agreed that published objective evidence on PE is limited to studies of men with lifelong PE engaging in vaginal intercourse. However, the committee regarded this definition as likely to apply to men with lifelong PE who engage in sexual activities other than vaginal intercourse. The panel concluded that there are insufficient published objective data to propose an evidence-based definition of acquired PE.

History of Definitions

For the first part of the 20th century there was no official definition of PE, although most psychiatrists and psychoanalysts considered PE as ejaculation within 30–60 seconds of vaginal intromission. However, there was no evidence to support this unwritten consensus [40]. This latency-based definition was rejected by Masters and Johnson, who defined PE as a man’s inability to delay ejaculation sufficient for the partner to reach orgasm in 50% of intercourse episodes [3]. However, an inherent problem exists in defining a man as dysfunctional based on the sexual responsiveness of his partner. Masters and Johnson’s partner response-based definition implied that any man whose partner has difficulty in reaching orgasm could be labeled a premature ejaculator and is at odds with the report that only 30% of women achieve orgasm during sexual intercourse regardless of the extent of their partner’s ejaculatory control and latency.

Diagnostic and Statistical Manual of Mental Disorders-Third Edition (DSM-III) and Diagnostic and Statistical Manual of Mental Disorders-Fourth Edition (DSM-IV) Definitions of PE

The first official definition of PE was proposed in 1980 by the American Psychiatric Association (APA) in the DSM-III [41]. In the DSM-III, PE was defined as “Ejaculation that occurs before the individual wishes it, because of recurrent and persistent absence of reasonable voluntary control of ejaculation and orgasm during sexual activity” [41]. The criterion of “reasonable voluntary control” was removed in the revision of the DSM-III (DSM-III-R) and in the subsequent DSM-IV and DSM-IV-TR editions and was replaced by the criterion of a “short ejaculation time.” In the
DSM-III-R, PE was defined as “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” [42]. The later DSM-IV and DSM-IV-TR editions maintained this definition but added the additional criterion “the disturbance causes marked distress or interpersonal difficulty” [27,43].

International Classification of Diseases (ICD-10) Definition of PE

The World Health Organization’s ICD-10 of 1993 defines PE as “The inability to control ejaculation sufficiently for both partners to enjoy sexual interaction” and as “an inability to delay ejaculation sufficiently to enjoy lovemaking, and manifest as either of the following: (i) 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) and (ii) ejaculation occurs in the absence of sufficient erection to make intercourse possible” [28]. The ICD-10 definition of PE limits the construct of “control” by the criterion “very short” ejaculation time of within 15 seconds but provides no supportive empirical evidence.

The Criterion of a “Short Ejaculation Time”

The DSM-IV-TR and the ICD-10 definitions of PE require that ejaculation time is “short” and “very short,” respectively. Although the ICD-10 definition specifies an ejaculation time cutoff of 15 seconds, the Diagnostic and Statistical Manual of Mental Disorders (DSM) definitions fail to provide any cutoff points. The absence of a time criterion in the DSM-III definition and a clear ejaculation time cutoff point in the subsequent DSM-III-R and DSM-IV definitions has resulted in the use of a broad range of latencies for the diagnosis of PE in clinical trials. Ejaculation latencies quoted in various published articles include within 1 minute [44], 2 minutes [45,46], 3 minutes [47], 4 minutes [48], 5 minutes [49–51], and 7 minutes after vaginal penetration [52]. These ejaculation latencies cutoff points were subjectively chosen by the various authors and were not based on objective measurements of ejaculation latency in men with PE. The failure of DSM definitions to specify an ejaculation latency cutoff point means that a patient in the control group of one study may very well be in the PE group of a second study, making comparison of studies difficult and generalization of their data to the general PE population impossible.

Authority-Based vs. Evidence-Based Definition of PE

The utility and application of the DSM-III, DSM-III-R, DSM-IV, DSM-IV-TR, and ICD-10 definitions of PE are limited as they are authority based and rely solely upon the opinion and clinical experience of experts who participated in the various DSM and ICD committees, i.e., expert opinion without explicit critical appraisal, and not well-controlled, evidence-based clinical research [53]. Similarly, the Second International Consultation of Sexual Dysfunctions (ICSD-2) and the American Urological Association (AUA) definitions of PE, which were derived from the DSM-IV-TR, must also be regarded as authority based [30,32,53].

The Need for an Evidence-Based Definition of PE

The validity of the DSM definitions continues to be the subject of debate with a substantial polarization of opinion. For critics of the DSM definitions, words such as “persistent,” “recurrent,” “minimal,” and “shortly after” are vague, multi-interpretable, and lack quantification [36,54,55]. They contend that the absence of a specific ejaculation time cutoff point to operationalize “shortly after penetration or before the person wishes” has led to the incorrect application of the DSM definitions in clinical research [56]. Many support the development of a new definition in the pending Diagnostic and Statistical Manual of Mental Disorders-Fifth Edition (DSM-V) [26,57–60]. However, criticism of the current DSM-IV-TR definition is not unanimous and a number of clinicians regard it as valid and regard both revision or the development of a new definition in the pending DSM-V as unnecessary [61,62].

However, the concern about the validity and application of the DSM-IV-TR definition is also shared by regulatory agencies such as the U.S. Food and Drug Administration. The lack of evidence-based criteria may serve as an obstacle for these authorities to interpret and assess data from clinical trials of PE investigational drugs. For these reasons, the ISSM Standards Committee has
recommended that a new evidence-based definition of PE should be formulated.

Rationale for the Inclusion of the Intravaginal Ejaculation Latency Time (IELT) in the ISSM Definition of PE

In 1994, Waldinger et al. introduced the IELT in an attempt to operationalize ejaculation latency in a definition of PE [63]. The IELT was defined as the time between vaginal intromission and intravaginal ejaculation [63]. This measure unequivocally defines ejaculatory latency and has contributed to more objective research in men with and without PE. Recently, it was proposed that Masturbation Ejaculation Latency Time, Oral Ejaculation Latency Time, and Anal Ejaculation Latency Time be adopted as measures for research in heterosexual or homosexual men with and without partners [64].

The IELT in Men with Lifelong PE

In a clinical study of a consecutive group of 110 men with complaints of lifelong PE, the duration of the IELT was measured by stopwatch operated by the woman partner [65]. Subjects were recruited by an advertisement offering treatment for PE and were not reimbursed for their participation. Men with ED, a history of alcohol abuse, and/or the current use of medication with sexual side effects were excluded. The diagnosis of lifelong PE was based on the self-reported occurrence of lifelong complaints of early ejaculation, and the patient expressed desire to delay ejaculation. The diagnosis was not based on application of the DSM-IV-TR or ICD-10 definitions of PE. The study showed that 40% of men ejaculated within 15 seconds, 70% within 30 seconds, and 90% within 1 minute after penetration. Only 10% ejaculated between 1 and 2 minutes. Participating couples reported that the use of a stopwatch did not significantly interfere with either sexual intercourse or the ejaculation time. Similar results were reported by McMahon in a retrospective case series of 1,346 consecutive men with PE and a mean IELT of 43.4 seconds [66]. These findings were confirmed in a third clinical study of 88 men with self-reported lifelong PE who actively sought treatment at a Sexual Disorder Outpatient Clinic. The diagnosis of PE was not based on application of the DSM-IV-TR or ICD-10 definition of PE [67]. In this study, IELT was self-estimated and a stopwatch was not used. This study showed that 30% of men ejaculated within 15 seconds, 67% within 30 seconds, 92% within 1 minute, and 8% between 1 and 2 minutes after penetration.

These studies suggest that the majority of men who actively seek treatment for lifelong PE (~90%) ejaculate within 1 minute of penetration. In men who ejaculate between 1 and 2 minutes after penetration, only 10% actively seek treatment for lifelong PE. On the basis of this evidence, the committee determined that 1 minute was an appropriate IELT cutoff point. An IELT cutoff of 1 minute captures 90% of men with PE who actively seek treatment and parallels the (very) short ejaculation time criteria of the DSM-IV-TR and ICD-10 definitions of PE. Further qualification of this cutoff to “about 1 minute” affords the clinician sufficient flexibility to also diagnose PE in the 10% of PE treatment-seeking men who ejaculate within 1–2 minutes of penetration without unnecessarily stigmatizing the remaining 90% of men who ejaculate within 1–2 minutes of penetration but have no complaints of PE.

The IELT in a Random Sample of Men in the General Male Population

Most community-based epidemiological studies are limited by their reliance on either patient self-report of PE or inconsistent and poorly validated definitions of PE. A recent industry-funded community-based age-ranging study of an unselected “normal” population of 500 heterosexual couples from five countries (the Netherlands, United Kingdom, Turkey, and Spain) involving stopwatch timing of the IELT during sexual intercourse has provided previously lacking normative IELT data [17]. This study demonstrated that the distribution of the IELT was positively skewed, with a median IELT of 5.4 minutes (range, 0.55–44.1 minutes). The median IELT decreased with age and varied between countries.

An epidemiological approach to assess disease risk and diagnostic criteria cutoff levels has been described for several diseases including osteoporosis, diabetes, and cardiovascular disease [68–72]. The prevalence of disease is by definition statistically limited to those members of the population within the 0.5 or the 2.5 percentile. In this study the authors regarded the 0.5 and 2.5 percentiles as acceptable standards of disease definition and reported that the 0.5 percentile equated to an IELT of 0.9 minute and the 2.5 percentile to an IELT of 1.3 minutes [17]. These normative data support the notion that IELTs of less than 1
minute are statistically abnormal compared to men in the general Western population. Using the underlying principles of disease risk assessment and the results of analysis of this normative data, Waldinger et al. have proposed that lifelong PE is a neurobiological dysfunction with a high lifetime risk of developing sexual and psychological problems [33].

Based upon collective data that reports that 90% of men complaining of lifelong PE ejaculate within 1 minute and only 10% ejaculate within 1–2 minutes, Waldinger et al. proposed that men with an IELT of less than 1 minute (belonging to the 0.5 percentile) are definitely at risk of lifelong PE (definite PE). In addition, the authors proposed that men with IELTs between 1 and 1.5 minutes (between 0.5 and 2.5 percentile) have a significant but less risk of lifelong PE (probable PE), and are probably at risk of lifelong PE (probable PE). The authors proposed that the severity of PE (non-symptomatic, mild, moderate, severe) is best defined by the presence and extent of associated psychological and sexual problems [33].

It should be noted that the use of the IELT as measure of ejaculatory performance has some limitations. The IELT can be confounded by several variables including the duration and content of foreplay, the sexual position, the depth, force, and frequency of penile thrusting, the period of time elapsed since the previous ejaculation, partner pelvic floor muscle tone, and the extent of partner vaginal lubrication. However, many of these confounders and the limitations they impose are only relevant in men with IELT values of more than 1 minute, where there is sufficient intercourse time for their impact to occur.

### Estimated IELT vs. Stopwatch IELT

Several authors report that estimated and stopwatch IELT correlate reasonably well or are interchangeable in assigning PE status when estimated IELT is combined with PROs [73–75]. In an industry-funded study, Pryor et al. reported that non-PE men overestimate their IELT to a larger extent than men with PE and IELT estimations for PE men correlate reasonably well with stopwatch-recorded IELT [74]. In another industry-funded study, Rosen et al. described the reliability of combining patient-estimated IELT and PROs of ejaculatory control, sexual satisfaction, and personal distress in predicting PE [75]. With PRO response scores of either “good” or “a little bit,” consistent with a DSM-IV-TR classification as non-PE or “poor” or “quite a bit,” consistent with a DSM-IV-TR diagnosis of PE, there was little variation in the probability of a PE diagnosis across a wide range of estimated IELT values (decreasing from ~98% to ~85% with increase in estimated IELT from 0 to 10 minutes). However, with mid-range PRO response scores of “fair” or “moderate,” the probability of a PE diagnosis decreased from ~65% to 18% with an increase in IELT from 0 to 10 minutes [74]. These findings do provide support for the use of self-estimation of IELT for the diagnosis of PE in clinical practice and as a measure of latency in a definition of PE.

This evidence (Table 1) strongly reinforces the value of including the construct of time-to-ejaculation in the ISSM definition of PE with the wording “... Ejaculation which always or nearly always occurs prior to or within about one minute of

### Table 1

Findings of key publications regarding the time-to-ejaculate in PE

<table>
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<th>Author/s</th>
<th>Summary of primary findings</th>
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| Waldinger et al. 1998 [65] | • 110 men with lifelong PE whose IELT was measured by the use of a stopwatch  
• 40% of men ejaculated within 15 seconds, 70% within 30 seconds, and 90% within 1 minute |
| McMahon, 2002 [66] | • 1,346 consecutive men with PE whose IELT was measured by the use of a stopwatch/wristwatch  
• 77% of men ejaculated within 1 minute |
| Waldinger et al. 2007 [67] | • 88 men with lifelong PE who self-estimated IELT  
• 30% of men ejaculated within 15 seconds, 67% within 30 seconds, and 92% within 1 minute after penetration  
• Only 5% ejaculated between 1 and 2 minutes |
| Waldinger et al. 2005 [17] | • Stopwatch IELT study in a random unselected group of 491 men in 5 countries  
• IELT had a positive skewed distribution  
• Application of 0.5 and 2.5 percentiles as disease standards  
• 0.5 percentile equated to an IELT of 0.9 minute and 2.5 percentile to an IELT of 1.3 minutes |
| Althof 1995 [73] | • IELT estimations for PE men correlate reasonably well with stopwatch-recorded IELT |
| Pryor et al. 2005 [74] | • IELT estimations for PE men correlate reasonably well with stopwatch-recorded IELT |
| Rosen et al. 2007 [75] | • Self-estimated and stopwatch IELT as interchangeable  
• Combining self-estimated IELT and PROs reliably predicts PE |

PE = premature ejaculation; IELT = Intravaginal Ejaculation Latency Time; PRO = Patient Reported Outcome.
vaginal penetration.” Time-to-ejaculation can be either self-estimated by the patient or measured with a stopwatch.

Inability to Delay Ejaculation (Ejaculatory Control)

The ability to prolong sexual intercourse by delaying ejaculation and the subjective feelings of ejaculatory control comprise the complex construct of ejaculatory control. The ability to delay ejaculation may be either innate or learned by modulating sexual excitement. Although there has been some limited success in conditioning other autonomic reflexes, it has yet to be empirically demonstrated that the ejaculatory reflex can be brought under voluntary control. Nor has it been demonstrated that men who have voluntary control are controlling their ejaculatory reflex. Voluntary delay of ejaculation is most likely exerted either prior to or in the early stages of the emission phase of the reflex but progressively decreases until the point of ejaculatory inevitability [76,77]. Virtually all men report using at least one cognitive or behavioral technique to prolong intercourse and delay ejaculation, with varying degrees of success, and many young men reported using multiple different techniques [78].

Self-taught cognitive techniques invariably involve distracting thoughts, most commonly sex-neutral cognitions such as thinking about sports, studies, or work, although a substantial proportion of men report using sex-negative cognitions that are specifically adverse to sexual arousal or focus upon negative consequences of sexual activity. The use of distracting thoughts is limited by the possible resultant decrease in the ability of men to attend to their partner’s level of arousal and may interfere with overall sexual functioning by decreasing their sexual satisfaction, creation of a negative association with sexual intercourse or the development of ED, especially in older men [79]. Other behavioral techniques employed by men include preemptive ejaculation prior to intercourse, condom use, pre-coital consumption of alcohol, pelvic floor muscle contraction and relaxation, breathing techniques and/or rate-limiting techniques such as temporary withdrawal, slowing down thrusting, thrusting in a circular motion or different or alternating intercourse positions.

In general, the greater the number of techniques employed, the greater men’s perceived ejaculatory control and IELT. Furthermore, there are no specific techniques that work for all men and the effectiveness of any specific technique at delaying ejaculation may be idiosyncratic to the man or to the particular situation.

Rationale for the Inclusion of Inability to Delay Ejaculation in the ISSM Definition of PE

Several authors have suggested that the inability to control or voluntarily delay ejaculation defines PE [80–84]. In an industry-funded internet survey of 1,158 research panel subjects, Rowland and coworkers classified 189 (16.3%) as having probable PE based upon DSM-IV-TR criteria and reported that 49.7% of PE subjects rated their control over ejaculation as “poor” or “very poor” compared to 1.4% of non-PE subjects [85]. However, diminished feelings of ejaculatory control, the subjective aspect of ejaculatory control, is difficult to translate into quantifiable terms and is not exclusive to men suffering from PE [78]. Consistent with this, attempts to both operationalize control and characterize the relationship between control and latency have reported conflicting results, making comparison across subjects or across studies problematic [18,65,78,86,87].

Grenier and Byers demonstrated a relatively weak correlation between ejaculatory latency and ejaculatory control (R = 0.51), sharing less than 10% of their variance [78]. They reported that some men with a brief ejaculatory latency time reported adequate ejaculatory control and vice versa, and concluded that the dimensions of ejaculatory control and latency are distinct concepts. In a subsequent study, Grenier and Byers reported similar results, with latency and control sharing only 12% of their variance, suggesting that these PROs are relatively independent [86]. In an industry-funded study, McMahon et al. reported that sildenafil treatment of subjects with lifelong PE significantly improved the score in the control domain of the Index of Premature Ejaculation. However, sildenafil treatment failed to significantly increase IELT. This discrepancy between control domain scores and IELT is testament to a “disconnect” between ejaculatory latency and ejaculatory control [88].

Waldinger et al. also reported a relatively weak correlation between ejaculatory control and stopwatch IELT (P = 0.06) in a group of 110 men with lifelong PE and a mean stopwatch IELT of 28 ± 29 seconds [65]. Little or no control over ejaculation was reported by 41% of subjects during foreplay and by 98% of subjects during intercourse. Although 26% of subjects reported full
contrary to this, several authors have reported a moderate correlation between the IELT and the feeling of ejaculatory control [18,75,87,89]. The correlation between measures of ejaculatory latency and control was positive and high for the age-matched group of 13 sexually functional men [87]. The correlation between measures of ejaculatory latency and control was positive and high for intercourse (R = 0.81, P < 0.001), but low or even negative for masturbation (R = -0.27, P = 0.27). Whereas functional men showed consistency in ejaculatory latency over coital and masturbatory activities, PE men exhibited much shorter latencies during coitus than during masturbation.

The relationship between ejaculatory control, IELT, and a diagnosis of PE was explored in two large multicenter, industry-funded observational studies with similar methodologies of subjects recruited from advertisements seeking men with and without PE [18,87]. The diagnosis of PE was based purely on the application of the DSM-IV-TR definition of PE by clinicians: IELT was not a criterion to establish the diagnosis of PE. Both studies reported that men diagnosed with PE had significantly lower mean ratings of control over ejaculation (P < 0.0001) [18,87]. Patrick et al. observed that 72% of men with PE reported ratings of “very poor” or “poor” for control over ejaculation compared to 5% in a group of normal controls [18]. Furthermore, more partners of PE subjects vs. partners of non-PE subjects gave ratings of “poor” or “very poor” for measures of control over ejaculation (53% vs. 3%, respectively). The strongest correlation between subject and partner measures was observed between the measure of control over ejaculation (R = 0.57). IELT was strongly positively correlated with control over ejaculation for subjects (R = 0.51) and partners (R = 0.46). Lower ratings for control over ejaculation were associated with shorter IELT, with “poor” or “very poor” control reported by 67.7%, 10.2%, and 6.7% of subjects with IELT <1 minute, >1 minute, and >2 minutes, respectively. Giuliano et al. reported “good” or “very good” control over ejaculation in only 13.2% of PE subjects compared to 78.4% of non-PE subjects [87]. However, the DSM-IV-TR definition of PE is authority-based and not evidence-based, has no support from controlled clinical and/or epidemiological studies, and is multi-interpretable [27,53]. It's use limits the application of the study conclusions regarding the relationship between PROs and IELT to the general population of PE men [90].

Several authors have reported post-hoc analyses of U.S. observational data using path analysis, a form of regression analysis, to assess the relationships between the Pros and IELT in men diagnosed with PE [75,87,91].

Patrick et al. reported that IELT showed a significant direct effect on control over ejaculation but did not show a significant direct effect on ejaculation-related personal distress or satisfaction with sexual intercourse [91]. However, control over ejaculation did show a significant direct effect on both ejaculation-related personal distress and satisfaction with sexual intercourse, with each showing direct effects on interpersonal difficulty related to ejaculation. In this study, the effect of IELT upon satisfaction and distress appears to be mediated via its direct effect upon control. In this study population, the subject’s perception of control over ejaculation is central to understanding how PE is associated with satisfaction with sexual intercourse and ejaculation-related distress. However, this study population had a mixed PE status and the relationship between control and IELT may differ in a more homogenous study group.

Rosen et al. used stepwise logistic regression analyses of several different linear models to assess the relationship between IELT and PROs and demonstrated that control over ejaculation and subject-assessed level of personal distress are more influential in determining PE status than IELT [75]. A subject reporting “very good” or “good” control over ejaculation is 90.6% less likely to have PE than a subject reporting “poor” or “very poor” control over ejaculation.

Giuliano et al. showed similar results in a path analysis of results obtained in the European observational study [87]. Correlation coefficients indicated that perceived control over ejaculation had a significant effect on satisfaction with sexual intercourse and personal distress related to ejaculation, whereas IELT did not have a direct effect on satisfaction with sexual intercourse and had only a small direct effect on ejaculation-related personal distress. These results support the notion that PE comprises a constellation of symptoms and is best diagnosed through a combination of IELT and validated, patient-reported set of PROs [92].

However, despite conflicting data on the relationship between control and latency, the balance of evidence supports the notion that the inability
to delay ejaculation appears to differentiate men with PE from men without PE [18, 85, 87]. This evidence (Table 2) provides sufficient empirical support for the inclusion of the construct of inability to delay ejaculation in the ISSM definition of PE with the wording “...is characterized by...the inability to delay ejaculation on all or nearly all vaginal penetrations.”

Table 2  Findings of key publications regarding ejaculatory control in PE

<table>
<thead>
<tr>
<th>Author/s</th>
<th>Summary of primary findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grenier and Byers [78]</td>
<td>• Relatively weak correlation between ejaculatory latency and ejaculatory control (R = 0.31)</td>
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<tr>
<td></td>
<td>• Ejaculatory control and latency are distinct concepts</td>
</tr>
<tr>
<td>Grenier and Byers [86]</td>
<td>• Relatively poor correlation between ejaculatory latency and ejaculatory control, sharing only 12% of their variance, suggesting that these PROs are relatively independent</td>
</tr>
<tr>
<td>Waldinger et al. [65]</td>
<td>• Little or no control over ejaculation was reported by 98% of subjects during intercourse</td>
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<td>• Weak correlation between ejaculatory control and stopwatch IELT (P = 0.06)</td>
</tr>
<tr>
<td>Rowland et al. [89]</td>
<td>• High correlation between measures of ejaculatory latency and control (R = 0.81, P &lt; 0.001)</td>
</tr>
<tr>
<td></td>
<td>• 72% of men with PE reporting ratings of “very poor” or “poor” for control over ejaculation compared to 5% in a group of normal controls</td>
</tr>
<tr>
<td>Patrick et al. [18]</td>
<td>• Men diagnosed with PE had significantly lower mean ratings of control over ejaculation (P &lt; 0.0001)</td>
</tr>
<tr>
<td></td>
<td>• “Good” or “very good” control over ejaculation in only 13.2% of PE subjects compared to 78.4% of non-PE subjects</td>
</tr>
<tr>
<td>Giuliano et al. [87]</td>
<td>• IELT was strongly positively correlated with control over ejaculation for subjects (R = 0.51)</td>
</tr>
<tr>
<td></td>
<td>• Men diagnosed with PE had significantly lower mean ratings of control over ejaculation (P &lt; 0.0001)</td>
</tr>
<tr>
<td></td>
<td>• “Good” or “very good” control over ejaculation had a significant effect on intercourse satisfaction and personal distress</td>
</tr>
<tr>
<td></td>
<td>• Control over ejaculation and subject-assessed level of personal distress are more influential in determining PE status than IELT</td>
</tr>
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<td>Patrick et al. [91]</td>
<td>• Effect of IELT upon satisfaction and distress appears to be mediated via its direct effect upon control</td>
</tr>
<tr>
<td>Rosen et al. [75]</td>
<td>• Subject reporting “very good” or “good” control over ejaculation is 90.6% less likely to have PE than a subject reporting “poor” or “very poor” control over ejaculation</td>
</tr>
</tbody>
</table>

PRO = Patient Reported Outcome; IELT = Intravaginal Ejaculation Latency Time; PE = premature ejaculation.

Negative Personal Consequences of PE

PE has been associated with negative psychological outcomes in men and their women partners [16, 18, 19, 25, 85, 87, 93–101]. The personal and/or interpersonal distress that results from PE may affect men’s quality of life and partner relationships and their self-esteem and self-confidence, and can act as an obstacle to single men forming new partner relationships [16, 18, 19, 25, 85, 87, 93–101].

Personal and interpersonal distress first appeared in the definition of PE in the 1994 publication of the DSM-IV [27]. Speculation as to why distress was included focuses on the concern that individuals who have impairments of sexual function but were satisfied with their sexual life would be unduly stigmatized and/or coerced to accept unwanted treatment. Subsequent definitions of sexual dysfunctions and PE, in particular, have maintained personal and/or interpersonal distress as a necessary criterion for diagnosis [30, 43, 102].

Distress, however, may not be the most appropriate term to capture the negative psychosocial consequences associated with PE. Qualitative research conducted as part of the development of new PE PROs informs us that words such as bother, frustration, and annoyance more accurately reflect patients’ and partners’ subjective negative experiences [103]. This notion is reinforced by research in other disease entities such as benign prostatic hyperplasia, where bother has been accepted as the preferred term to capture the negative experiences associated with the disease [104].

Three forms of distress appear in the definitions of PE. They are personal distress for the man, personal distress for the partner, and interpersonal distress. The DSM-IV-TR includes all three forms of distress; the AUA and the ICSD-2 definitions include only personal and partner distress [30, 43, 102]. Partner and/or interpersonal distress, while important as negative psychosocial outcomes, would not be germane to the diagnosis of men with PE as not all men have partners.

Rationale for the Inclusion of Negative Personal Consequences in the ISSM Definition of PE

In the last decade several articles have appeared providing limited but sufficient evidence for the inclusion of personal distress in the definition of PE [16, 18, 19, 85, 87, 93–96, 98, 100, 101]. However,
The data are not as strong for the inclusion of interpersonal distress [25,97]. These reports employed different methods to assess distress in men with PE, their partners, and the relationship. They include quantitative validated questionnaires, non-validated measures, Internet surveys, postal surveys, and thematic assessment of qualitative reviews.

Ten studies examined the psychosocial and quality-of-life consequences associated with PE men and their partners (Table 3) [16,18,25,85,87,93–98]. Despite the use of different methodologies and outcome measures, all these studies suggest that PE is associated with negative consequences for the man, his partner, and their relationship.

For example, Patrick et al. conducted a 4-week industry-funded observational study of 1,587 men, with 207 diagnosed with PE by clinicians employing DSM-IV-TR criterion and with 1,380 judged by clinicians not to have PE [18]. Partner-held stopwatch IELTs were recorded for each intercourse event, and men and their partners independently completed four PROs assessing control over ejaculation, satisfaction with sexual intercourse, personal distress, and interpersonal difficulty.

There were significant differences in the responses of men with and without PE in responding to the PRO questions measuring personal distress, interpersonal difficulty, and satisfaction. Contrasting men with and without PE, 64% vs. 4% of men reported being “quite a bit” or “extremely” personally distressed, while 31% vs. 1% indicated “quite a bit” or “extremely” distressed for interpersonal difficulty and 31% vs. 1% reported rated “very poor” or “poor” for satisfaction with sexual intercourse. The divergent pattern observed for personal distress suggests that this construct has discriminative validity in diagnosing men with and without PE. The data for satisfaction and interpersonal distress, while statistically significant, were not as strong.

Similarly, in a recent, large European industry-funded observational study using the same four questions (the Premature Ejaculation Profile), Giuliano et al. demonstrated that substantially more men with PE and their partners were “extremely” or “quite a bit” distressed compared to the non-PE groups (43.9% vs. 1.4% for men; 30.2% vs. 1.0% for partners) [87]. Finally, in both Patrick et al.’s and Giuliano et al.’s studies a moderate correlation between the couples’ ratings for personal distress (r = 0.53, r = 0.49, respectively) was observed, adding to the convincing body of evidence regarding the negative psychosocial outcome for this dysfunction [18,87].

Additionally, 4 of 11 studies showed that PE has a marked effect on the quality of life of men (Table 1) [16,19,94,95]. McCabe reported that sexually dysfunctional men, including men with PE, scored lower on all aspects of intimacy (emotional, social, sexual, recreational, and intellectual) and had lower levels of satisfaction compared to sexually functional men ($P < 0.001$ or $P < 0.01$).

### Table 3  Findings of key publications regarding the negative personal consequences of PE

<table>
<thead>
<tr>
<th>Author/s</th>
<th>Summary of primary findings</th>
</tr>
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<tbody>
<tr>
<td>Patrick et al. [18]</td>
<td>Using the validated Premature Ejaculation Profile (PEP), 64% of men in the PE group vs. 4% in the non-PE group reported personal distress</td>
</tr>
<tr>
<td>Giuliano et al. [87]</td>
<td>On the PEP, 44% of men in the PE group vs. 1% of men in the non-PE group reported personal distress</td>
</tr>
<tr>
<td>Rowland et al. [95]</td>
<td>Men in highly probable PE group reported greater distress vs. men in non-PE group on the PEP scale</td>
</tr>
<tr>
<td>Rowland et al. [85]</td>
<td>30.7% of probable PE group, 16.4% of possible PE group vs. 7.7% of non-PE group found it difficult to relax and not be anxious about intercourse</td>
</tr>
<tr>
<td>Porst et al. [93]</td>
<td>Depression reported by 20.4% of PE group vs. 12.4% of non-PE group</td>
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<td></td>
<td>Excessive stress in 28% of PE group vs. 19% of non-PE group</td>
</tr>
<tr>
<td></td>
<td>Anxiety in 24% of PE group vs. 13% on non-PE group</td>
</tr>
<tr>
<td>McCabe [96]</td>
<td>Sexually dysfunction men, including those with PE, scored lower than sexually functional men on all measures of intimacy on the Psychological and Interpersonal Relationship Scale</td>
</tr>
<tr>
<td>Symonds et al. [16]</td>
<td>68% reported self-esteem affected by PE. Decreased confidence in sexual encounter.</td>
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<td></td>
<td>Anxiety reported by 36% (causing PE or because of it)</td>
</tr>
<tr>
<td></td>
<td>Embarrassment and depression also cited because of PE</td>
</tr>
<tr>
<td>Dunn et al. [94]</td>
<td>Strong association of PE with anxiety and depression on the Hospital and Anxiety Scale</td>
</tr>
<tr>
<td>Hartmann et al. [25]</td>
<td>56% of PE group reported partner’s behavior and reaction to PE was positive and 23% reported it was negative</td>
</tr>
<tr>
<td>Byers et al. [97]</td>
<td>Men with PE and their partners reported slightly negative impact of PE on personal functioning and sexual relationship but no negative impact on overall relationship</td>
</tr>
</tbody>
</table>

PE = premature ejaculation.
[96]. In an industry-funded study, Rowland et al. showed that men with PE had significantly lower total Self-Esteem And Relationship Questionnaire scores and lower confidence and self-esteem compared to non-PE groups (all $P \leq 0.001$) [95]. PE men rated their overall health-related quality of life lower than men without PE ($P \leq 0.001$ or $P \leq 0.006$). Symonds et al. and Dunn et al. independently demonstrated a strong association between sexual confidence, anxiety, and in some cases depression with PE [16,94].

This evidence (Table 3) reinforces the value of including personal distress in the ISSM definition of PE with the wording “is characterized by . . . negative personal consequences, such as distress, bother, frustration and/or the avoidance of sexual intimacy.” Distress, frustration, and/or bother capture the negative psychological consequences of PE and are important constructs that discriminate between men with PE and those without PE. As some men do not have partners and as partner distress and interpersonal distress are not universally applicable to all men, partner distress and interpersonal distress should not be included in the definition of PE [25,97].

**Sexual Satisfaction**

Men with PE report lower levels of sexual satisfaction compared to men with normal ejaculatory latency [18,87].

**Rationale for the Exclusion of Satisfaction in the ISSM definition of PE**

Patrick et al. reported ratings of “very poor” or “poor” for sexual satisfaction in 31% of subjects with PE compared to 1% in a group of normal controls [18]. Furthermore, more partners of PE subjects vs. partners of non-PE subjects gave ratings of “poor” or “very poor” for measures of sexual satisfaction with sexual intercourse (28% vs. 2%, respectively). However, caution should be exercised in assigning lower levels of sexual satisfaction solely to the effect of PE, and contributions from other issues that are difficult to quantify such as reduced intimacy, dysfunctional relationships, poor sexual attraction, and poor communication should not be ignored. This is supported by the report of Patrick et al. that despite reduced ratings for satisfaction with shorter IELTs with “poor” or “very poor” intercourse satisfaction reported by 25.4%, 3.6%, and 2.0% of subjects with an IELT <1 minute, >1 minute, and >2 minutes, respec-

**Conclusion**

In the last decade, substantial progress has been made in the development of the evidence-based methodology of PE epidemiological and drug treatment research using the objective IELT and subjective validated PROs. However, this research has been restricted by the lack of an evidenced-based definition of PE. Existing definitions of PE are vague, multi-interpretable, primarily conceptual in nature, lack specific operational criteria, and rely to a large extent on expert opinion without explicit critical appraisal rather than on the findings of evidence-based clinical research.

Evidence-based definitions seek to limit errors of classification and thereby increase the likelihood that existing and newly developed therapeutic strategies are truly effective in carefully selected dysfunctional populations [39]. One method of decreasing diagnostic errors is to employ a multivariate definition with several diagnostic criteria rather than a single, specified IELT cutoff point. Such a definition serves to broaden the focus of clinicians and investigators from the IELT alone by inclusion of important subjective variables such as perceived control and distress/bother regarding ejaculatory latency. A multivariate definition of PE provides the clinician a more discriminating diagnostic tool. If a multivariate definition is used, men who ejaculate in less than 1 minute but report adequate control and no personal negative consequences related to their rapid ejaculation do not merit the diagnosis of PE. Similarly, men who have IELTs of 10 minutes but report poor control, dissatisfaction, and personal negative consequences also fail to meet the criteria for PE.

Although there have been several recent large evidence-based observational studies, many are methodologically flawed and there is an urgent need for standardization of PE observational, intervention, and intervention preference trial methodology. The methodology of many of these studies is polarized, either focusing on IELT alone.
with scant attention to PROs or concentrating upon the PROs of control, satisfaction, and distress in men diagnosed as having PE by application of the DSM-IV-TR with IELTs as high as 20 minutes. Conclusions regarding the relationship between PROs and IELT based on data from studies with inadequately selected trial groups must be regarded with some caution and cannot be reliably generalized to subjects with this condition.

After critical evaluation of the published data, the committee unanimously agreed that the constructs that are necessary to define PE are time from penetration to ejaculation, inability to delay ejaculation, and negative personal consequences from PE and recommended the following definition of lifelong PE.

Lifelong PE is a male sexual dysfunction characterized by

- ejaculation that always or nearly always occurs prior to or within about 1 minute of vaginal penetration;
- the inability to delay ejaculation on all or nearly all vaginal penetrations; and
- negative personal consequences such as distress, bother, frustration, and/or the avoidance of sexual intimacy.

The committee also agreed that the 1-minute IELT cutoff point should not be applied in the most absolute sense, as about 10% of men seeking treatment for lifelong PE have IELTs of 1–2 minutes. The phrase “within about 1 minute” must be interpreted as giving the clinician sufficient flexibility to diagnose PE also in men who report an IELT as long as 90 seconds. A diminished ability to delay ejaculation is only valid as a criterion of lifelong PE if the same individual always or nearly always ejaculates within about 1 minute. The ISSM definition of lifelong PE is intended to serve as an international standard for defining this common sexual dysfunction. It is not intended to be a means of measuring the effect of the pharmacologic treatment of PE or to erroneously suggest that improving control and reducing distress without improving the IELT indicates drug efficacy.

This definition intentionally embodies a degree of diagnostic conservatism and flexibility for several reasons. First, a conservative and flexible definition provides a more realistic prevalence of the dysfunction. Second, it would help to establish PE as a bona fide sexual dysfunction rather than a lifestyle condition where men are simply seeking to enhance their sexual function. Third, it would help to ensure greater confidence in the efficacy of new and existing treatments and strengthen the likelihood that regulatory agencies might approve new efficacious and safe compounds for this dysfunction [39].

A limitation of the definition is its application to only heterosexual men engaging in vaginal intercourse. However, as there are few studies available on PE research in homosexual men, and as the major focus of the committee was to formulate a definition on evidence-based data, it has been decided to restrict the definition to heterosexual men engaging in vaginal intercourse.

After a critical evaluation of the published data, the committee was unable to identify sufficient published objective data to craft an evidence-based definition of acquired PE. It is hoped that future studies will generate data to formulate such a definition. The committee encourages further research into acquired PE, PE in homosexual men, and PE during other forms of heterosexual sexual expression.

We are grateful to the ISSM for its leadership in assembling and encouraging the committee members in devising the evidence-based PE definition. We hope this definition will encourage and facilitate further research into the prevalence of both lifelong and acquired PE, the development of new tools and PROs for both the diagnosis and assessment of treatment outcomes, and the development of new pharmacologic and psychological treatment.

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Conflict of Interest: C.G. McMahon: Johnson & Johnson—Consultant, Principal Investigator, Advisory Board, Speaker; Bayer Schering—Investigator, Advisory Board, Speaker; Pfizer—Advisory Board, Principal Investigator, Speaker; Plethora Solutions—Advisory Board, Speaker; Futura Medical—Advisory Board; Rexhana—Advisory Board. S. Althof: Bio-Sante—Principal Investigator; Boeringer Ingelheim—Sub Investigator; GSK—Advisory Board, Consultant; Johnson & Johnson—Advisory Board, Speaker; Lilly—Advisory Board, Speaker; Palitan—Advisory Board, Speaker; Pfizer—Speaker; Plethora—Advisory Board, Principal Investigator; sanofi-aventis—Advisory Board. M.D. Waldinger: Pfizer—Principal Investigator; Plethora Solutions—Advisory Board, Speaker. H. Porst: Johnson & Johnson—Consultant, Investigator, Speaker; Cilag-Janssen—Consultant, Investigator, Speaker; Bayer Schering—Consultant, Investigator, Speaker; Lilly—Consultant, Investigator, Speaker; Pfizer—Consultant, Investigator, Speaker. J. Dean: Bayer Schering—Consultant, Pfizer—Consultant; Lilly—Consultant; Boehringer-Ingelheim—Consultant; Pro-Strakan—Consultant; Plethora Solutions—Consultant; Johnson & Johnson—Consultant. I. Sharlip: Johnson & Johnson—Consultant, Speaker; Lilly—Consultant, Speaker; Pfizer—Consultant, Speaker; Plethora Solutions—Advisory Board.

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