SEXUAL MEDICINE

REVIEW

EJACULATION DISORDERS

The Tenuous Role of Distress in the Diagnosis of Premature Ejaculation: A Narrative Review

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ABSTRACT

Background: Unlike the other 2 criteria for diagnosing premature ejaculation (PE), namely lack of ejaculatory control and short ejaculation latency (EL), the role of bother/distress has received only minimal consideration and investigation.

Aim: The specific aim was to determine both why distress is included in the PE diagnosis and whether such inclusion is advantageous to achieving better diagnostic outcomes. To this end, the review explored the historical and theoretical underpinnings of the inclusion of "bother/ distress" in the diagnosis of PE, with reference to the larger role that distress has played in the diagnosis of mental disorders, in an attempt to understand the utility (or lack thereof) of this construct in making a PE diagnosis.

Methods: We reviewed the role of bother/distress across current professional definitions for PE and then expanded this discussion to include the role of distress in other sexual dysfunctions. We then included a brief historical perspective regarding the role that distress has played in the diagnosis of PE. This discussion is followed by a deeper look at 2 nosological systems, namely DSM and ICD, to allow perspective on the inclusion of the bother/ distress construct in the diagnosis of mental and behavioral disorders, including the assumptions/arguments put forward to include or exclude bother/distress as an important criterion underlying various professional assumptions.

Outcome: Determination of the value and/or need of including bother/distress as a necessary criterion for the diagnosis of PE.

Results: Based on the research literature, bother/distress does not appear to be as critical for a PE diagnosis as either the lack of ejaculatory control or short EL. It is the weakest of the differences among men with and without PE, and recent evidence suggests that its inclusion is generally redundant with the severity of the 2 other criteria for PE, ejaculatory control and EL.

Clinical Translation: Bother/distress appears to serve little purpose in the diagnosis of PE yet its assessment may be important for the treatment strategy and for assessing treatment effectiveness.

Strengths and Limitations: This review did not provide a critical analysis of the literature regarding the role of bother/distress in PE, but rather focused on its potential value in understanding and diagnosing PE.

Conclusion: Although bother/distress appears to add little to the improvement of accuracy for a PE diagnosis, understanding and assessing the man's or couple's experience of distress has important implications for the treatment strategy and focus, as well as for assessing treatment success. **Rowland DL, Cooper SE. The Tenuous Role of Distress in the Diagnosis of Premature Ejaculation: A Narrative Review. Sex Med 2022;10:100546.**

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Key Words: Premature Ejaculation; Diagnosis; Bother/Distress; Ejaculatory Control; Ejaculation Latency; Mental Disorders

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INTRODUCTION

In the year 2000, the American Psychiatric Association (APA) introduced the three-pronged diagnostic criteria for premature ejaculation (PE): "ejaculation upon minimal stimulation;" "before the person wishes it" (indicating a lack of self-efficacy); and causing "marked distress or interpersonal difficulty."[1] These

initial criteria—relying primarily on expert opinion—were subsequently modified in 2008 based on the limited empirical support available at the time by the International Society of Sexual Medicine (ISSM).[2] In shorthand, these criteria are nowadays often expressed as: a short ejaculation latency (EL) upon minimal stimulation; a lack of ejaculatory control; and negative consequences such as bother/distress.[2] Subsequently, these criteria have been widely embraced by other professional organizations, with language, lexicon, and qualifiers modified to fit their particular stakeholders.[3−6]

The inclusion of these specific criteria relied on consensus panels drawing from several seminal studies that lent preliminary support to each prong of the definition; subsequently, these criteria became benchmarks for establishing the efficacy of various treatment strategies for men with PE (eg,[7,8]). However, most of the initial research supporting the PE criteria focused on the first two criteria mentioned above, with substantial debate as to what timeframe constituted a "short" EL, and whether the most critical criterion for PE was that of a short EL or that of a lack of ejaculatory control.[9]

Regarding the first issue, EL, initial consensus identified 60 sec (1 min) as a cut-off for defining a short latency, but data accumulated over the following decade using standard methodologies for validation of measures suggested an EL criterion closer to 2 min, currently reflected in the 2010 European Association of Urology (EAU) guidelines[10] and more recently in the revision of PE criteria carried out by the American Urological Association (AU).[4] Regarding ejaculatory control, path analysis supports the position that this condition/concept is central to the diagnosis of PE, its severity, PE-related distress, diminished sexual satisfaction, and perceived treatment benefits.[11−13] Accordingly, although the specific wordings differ, ISSM, APA, AUA, and the World Health Organization's (WHO) International Classification of Disease, 11th revision (ICD-11) all use language that recognizes the central role of lack of ejaculatory control in the diagnosis of PE.[2−5]

Despite an initial flurry of research on these 2 PE criteria, subsequent research has since dwindled, contrary to the usual process of developing diagnostic criteria—one that is ongoing and dynamic[14,15] and that consistently critiques existing criteria; generates new data to support, revise, refine, or discard them; and leads to consensus across professional groups. In contrast with the modest research effort on EL and ejaculatory control, almost no attention has been paid to the third PE criterion, namely, the negative consequences of the PE (expressed in shorthand as "bother/distress"). Indeed, a review of the literature reveals that this prong of the PE diagnostic criterion has received only scant and scattered theoretical and empirical investigation since 2007.[16−18]

So, what is the role of bother/distress in the diagnosis of PE? Men with PE often express concern, bother, distress, or other negative personal, interpersonal/relational, or partner consequences resulting from their sexual dysfunction.[2,4] These psychological and relationship consequences typically represent a "construct," that is, an unobservable, latent variable that is presumed to exist, is an attribute of people (or animals), and is used to help explain or predict variation in responses or behavior.[15] While the study of psychological or subjective variables regularly relies on many such constructs to explain variation in behaviors (eg, arousal, emotion, stress, and sexual desire), compared with directly "observable" variables, these nonobservable constructs are difficult to define and often lack consensus regarding their optimal operationalization. For example, given the broad nature of this construct, bother/distress has stood as an abbreviated proxy for any and all "negative consequences of PE," which encompass a wide range of *psychological, behavioral,* and *interpersonal* effects on the patient or his partner. Terminology used to elaborate negative psychological consequences has include descriptors such as bothered, dissatisfied, anxious, concerned, depressed, frustrated, ashamed, self-disgusted, embarrassed, and others. Negative behaviors have included, but not been limited to, verbal catastrophizing about the negative impact of PE, avoidance of physical intimacy, or profuse postcoital apologizing.[4,19]

GOALS AND STRATEGY

In this paper, we address an issue initially raised in the first ISSM consensus panel: whether "bother/ distress" should be a requirement for a PE diagnosis.[20] The specific aim was to determine both why distress is included in the PE diagnosis and whether such inclusion is advantageous to achieving better diagnostic outcomes. Our consideration in this paper is historical as well as theoretical. We (i) review the role of bother/distress across current professional definitions for PE and then briefly expand this discussion to include the role of distress in other sexual dysfunctions; (ii) include a brief historical perspective regarding the role that distress has played in the diagnosis of PE; (iii) review 2 nosological systems, namely DSM and ICD, to allow perspective on the inclusion of the bother/distress construct in the diagnosis of general mental and behavioral disorders, including the assumptions/arguments put forward to include or exclude bother/distress as an important criterion underlying various professional definitions. The preceding analysis is intended to clarify both parallel and divergent approaches for the diagnostic role of distress between the major nosological systems *in general* and the diagnosis or PE *specifically*, enabling us to (iv) circle back to the role of distress in the diagnosis of PE, reviewing the empirical support underlying its putative involvement; and (v) discuss the current value of assessing distress in diagnosing PE, in understanding the lived experiences of men/couples dealing with PE, and in developing an effective treatment strategy.

METHODOLOGY

To investigate this issue, we took a 3-pronged approach. First, we obtained and reviewed current and archived records of various professional societies to determine both the emergence and

current status of "bother/distress" in the definition and diagnostic criteria for PE. In addition, we reviewed current and archived text from APA (DSM) and ICD to understand the prior and current role of "distress" and/or "harm" in the characterization of mental and psychological disorders.

Second, we conducted a systematic literature search of all papers since the year 1990 intersecting the constructs of bother/distress and PE using MEDLINE, DynaMed, PsycArticles, and PsycInfo databases. Typical keywords expanded upon PE with such terms as early ejaculation, ejaculation praecox, rapid ejaculation, and ejaculatory disorders. Typical keywords expanding upon the construct of "distress" included terminology such as bother, clinical distress, concern, guilt, frustration, shame, and avoidance. Results of these searches were augmented by resources known to the authors through their expertise, as each author has had extensive experience in research, publication, and workshop presentations in the respective fields of sexual and psychological dysfunction and intervention. Unless redundant, all empirical papers directly relevant to the focus of this paper (distress in the diagnosis/definition of PE) were included in the respective sections of the article; review papers and chapter information were used if and when they contributed new insight to the topic.

Third, we conducted an eclectic literature search dating back to the year 2000 intersecting "distress" and/or "harm" with the diagnosis and definition of mental and psychological disorders. We opted to focus on two current review/position papers offering point and counterpoint perspectives to this issue. Related papers were cited to reinforce or elaborate upon specific issues as needed.

RESULTS

Bother/Distress in the Current Diagnosis of PE and Other Sexual Problems

We begin with three observations. First, all current professional definitions of PE from ISSM, APA/DSM-5, AUA, EAU, and ICD-11 include "distress" or a comparable term indicating a negative consequence resulting from PE symptomology. Although exact terminology differs, the underlying construct of bother/distress is apparent in all five definitions (Table 1).

Second, and in contrast with PE, diagnosis of another sexual dysfunction in men, namely erectile dysfunction (ED), may occur in the absence of "bother/distress. While it makes sense that APA/DSM—which focuses on mental and psychological health—includes the condition of distress in its definition of ED,[3] neither AUA nor the American Academy of Family Physicians (AAFP) does so.[21,22] Interestingly, ICD-11 does include "clinical distress" as part of its ED definition.[23] The fact that bother/distress is a stipulation for a PE diagnosis but is only sometimes considered relevant for an ED diagnosis suggests that

Table 1. Current professional definitions of PE from ISSM, APA/DSM-5, AUA, EAU, and ICD-11, with wording regarding distress italicized and in bold

International Society of Sexual Medicine
A unified definition of both acquired and lifelong PE as a male sexual dysfunction characterized by (i) ejaculation that always or nearly always occurs prior to or within about 1minute of vaginal penetration from the first sexual experience (lifelong PE) or a clinically significant and bothersome reduction in latency time, often to about 3 minutes or less (acquired PE); (ii) the inability to delay ejaculation on all or nearly all vaginal penetrations; and (iii) ***negative personal consequences, such as distress, bother, frustration, and/or the avoidance of sexual intimacy***.
American Psychiatric Association (DSM-5)
A persistent or recurrent pattern of ejaculation occurring during partnered sexual activity within approximately 1 minute following vaginal penetration and before the individual wishes. The symptom must be present for at least 6 months and must be experienced on almost all or all (approximately 75%-100%) occasions of sexual activity and ***causes clinically significant distress***. The sexual dysfunction is not better explained by a nonsexual mental disorder or as a consequence of severe relationship distress or other significant stressors and is not attributable to the effects of a substance/medication or another medical condition.
American Urological Association
Lifelong premature ejaculation is defined as poor ejaculatory control, ***associated bother***, and ejaculation within about 2 minutes of initiation of penetrative sex that has been present since sexual debut. Acquired premature ejaculation is defined as consistently poor ejaculatory control, ***associated bother***, and ejaculation latency that is markedly reduced from prior sexual experience during penetrative sex.
European Association of Urology (adopted the ISSM definition)
Ejaculation that always or nearly always occurs prior to or within about 1 minute of vaginal penetration (lifelong PE) or a clinically significant and bothersome reduction in latency time, often to about 3 minutes or less (acquired PE); inability to delay ejaculation on all or nearly all vaginal penetrations; ***negative personal consequences, such as distress, bother, frustration, and/or the avoidance of sexual intimacy.***
International Classification of Disease, 11 edition (World Health Organization)
Male early ejaculation is characterized by ejaculation that occurs prior to or within a very short duration of the initiation of vaginal penetration or other relevant sexual stimulation, with no or little perceived control over ejaculation. The pattern of early ejaculation has occurred episodically or persistently over a period at least several months and is associated with ***clinically significant distress***.

these two male sexual dysfunctions are in some way fundamentally different. Indeed, we and others have previously argued that PE—in contrast with ED—occurs primarily within the context of a relationship and therefore the PE-related distress is largely the product of sexual and interpersonal interaction with a partner,[24] where negative feelings in the man arise primarily due to the detrimental effects of the rapid ejaculation on the sexual satisfaction of the partner. Aligned with this premise, recent studies have found the bother/distress in men with PE during masturbation is greatly attenuated (although not absent) relative to distress during partnered sex, although it is still greater than levels seen in non-PE men.[25,26]

Third, all other sexual dysfunctions elaborated by APA/DSM-5—for example, male problems that include delayed ejaculation and hypoactive sexual desire disorder, and female problems that include female orgasmic disorder, female sexual interest/arousal disorder, and genito-pelvic pain/penetration disorder—make specific reference to the impairment "associated with clinically significant distress in the individual." The inclusion of "clinically significant distress" suggests that, even in instances where the etiology of the problem may be primarily physiological (eg, genital pain, erectile dysfunction), its diagnosis and treatment may also include significant psychological issues.[3]

Beyond DSM-5, all sexuality-related disorders in ICD-11 also include the general rubric of "associated with clinically significant distress".[23] This current terminology essentially retains the ICD-10 definition for mental disorders as "a clinically recognized set of symptoms or behaviors associated *in most cases with distress* (italics added) and with interference with personal functions." ICD-11 also clearly stipulates that for an individual "satisfied with his/her pattern of sexual experience and activity, even if it is different from what may be satisfying to other people or what is considered normative in a given culture or subculture, a sexual dysfunction should not be diagnosed." In short, ICD-11 states that if bother/distress is not a component of the sexual impairment, it should not be viewed as a dysfunction. Furthermore, because ICD-11 eliminated the distinction between "organic" and "nonorganic" (the latter presumably including psycho-socio-cultural factors), it added etiological qualifiers that essentially retain elements of the organic/non-organic distinction. Examples include PE associated with a medical condition, procedure, or injury; psychological or behavioral factors, including mental disorders; substance use or medication; relationship factors; and cultural factors.[5]

Bother/Distress in the PE Diagnosis from a Historical Perspective

In the previous section we showed that "distress" is universal in current APA and ICD definitions of PE and as well as in definitions of other sexual dysfunctions, but we also note that other sexual dysfunctions—defined by other professional organizations—may not necessarily include "distress" (eg, for ED). In this next section, we briefly review prior DSM and ICD definitions of PE in order to specify when "distress" emerged as a criterion for a PE diagnosis (see[19] for a review).

The first official definition of PE, established in 1980 by the American Psychiatric Association (APA) in the DSM-III,[27] focused solely on the subjective self-efficacy construct of "persistent absence of reasonable voluntary control" and did not include any comment on EL or distress. In the subsequent DSM-III-R (1987),[28] DSM-IV (1994),[29] and DSM-IV-TR (2000)[1] definitions, this criterion was replaced by the subjective criteria of a "short ejaculation time", "before the person wishes it" and causes "marked distress or interpersonal difficulty, thus marking the initiation of the pattern of including bother/distress as a criterion for PE and establishing for the first time the three prongs currently used in the ISSM, DSM, and AUA diagnostic definitions of PE. Despite the inclusion of these 3 criteria, none was operationally defined at the time; and even today, only EL has been operationally defined (eg, [2,4,30]). Operational definitions for either ejaculatory control or bother/distress have not been offered, although the latter criterion has generally been characterized with the phrase "clinically significant distress."[2,4,5] This vaguely-defined description is presumably intentional, leaving discretion to clinical expertise in rendering the final diagnostic decision.

ICD has followed a different path for inclusion of distress. PE did not appear in ICD until the ninth revision (ICD-9) in 1979,[31] when it was identified as a disorder characterized "by persistent or recurrent ejaculation before or after penetration and before the person wishes it," or by "the emission of semen and seminal fluid during the act of preparation for sexual intercourse, that is, before there is penetration, or shortly after penetration." Concepts of both a short ejaculation latency and a lack of ejaculatory control ("before the person wishes it") were included, but with no mention of "bother/distress." ICD-10 (eg, versions 2008−2019)[32] describes PE as "the inability to control ejaculation sufficiently for both partners to enjoy sexual interaction," again referring to a lack of control, but also hinting at the idea of bother/distress, given the language about both partners not enjoying the interaction. The most recent iteration of ICD (ICD-11:2020[5]), characterizes "male early ejaculation" as "ejaculation that occurs prior to or within a very short duration of the initiation of vaginal penetration or other relevant sexual stimulation, with no or little perceived control over ejaculation. The pattern of early ejaculation. . .is associated *with clinically significant distress*" (italics added) Thus, for this iteration, distress is clearly indicated (although not operationalized), bringing the diagnostic criteria in line with the 3 prongs identified by other professional groups.

Thus, both ICD and DSM definitions have evolved over revisions (with DSM-5-TR indicating no further change) such that now both definitions include distress as an important criterion in the diagnosis of PE. We further note that the ISSM definitions of lifelong and acquired PE have both included distress from

their inception,[33] as has the AUA definition in both prior[30] and current versions[4] (https://www.auanet.org/guidelines/archived-documents/premature-ejaculation-guideline).

The General Role of Distress in Diagnosing Mental and Sexual disorders (DSM and ICD)

Given the universal inclusion of bother/distress in definitions and diagnostic criteria for PE by professional organizations, one might assume that its inclusion has been based upon both strong theoretical and empirical support. On the contrary, the issue of distress as a diagnostic criterion for PE represents a sidebar to a much broader conversation regarding the role of distress in mental health and psychological diagnoses.[34−40]. Thus, understanding the role of distress in PE is perhaps better understood within the larger historical and cultural framework of its role as a potential factor in the accurate diagnosis of psychological health and mental disorders in general. Advocates both for and against the inclusion of "distress" in such diagnoses tend to surface most strongly at times of nosological revisions, and in the more recent versions of DSM and ICD, those advocating for its inclusion have generally been more successful than those critical of its inclusion.[2−5]

We begin this discussion by noting that negative consequences such as bother/distress are typically conceptualized under the larger rubric of "harm" in nosologies such as DSM and ICD. "Harm" has included such synonyms as "pain," suffering," "anguish," "grief," "loss," "distress," and "torment," with terminology used in PE definitions such as bother/distress, interpersonal difficulty, concern, and so on, representing forms of harm to either oneself or one's partner (and thus to the relationship).

From a historical perspective, both DSM-IV and DSM-IV-TR retained the language of both DSM-III and DSM-III-R.[1,27−29] "In DSM-IV, each of the mental disorders is conceptualized as a clinically significant behavioral or psychological syndrome or pattern that occurs in an individual and that is *associated with present distress* (eg, a painful symptom) or disability (ie, impairment in one or more important areas of functioning) or with a significantly increased risk of suffering death, pain, disability, or an important loss of freedom." That is, these earlier versions allow for "distress" *or* "disability"—the latter elaborated as impairment in functioning—in the diagnostic process, with the inference that one may substitute for the other. As such, distress is not a requirement, but may be part of a classification process in which either or both may apply.

A key change from DSM-IV(-TR) to DSM-5 (and most recently DSM-5-TR) was both the clarification and qualification of the harm component of the definition[1,3]: DSM-5 includes a definition of the needed elements for *a mental disorder* in the following:

"A mental disorder is a syndrome characterized by clinically significant disturbance in an individual's cognition, emotion regulation, or behavior that reflects a dysfunction in the psychological, biological, or development processes underlying mental functioning. Mental disorders *are usually associated with significant distress or disability* (italics added) in social, occupational, or other important activities. An expectable or culturally approved response to a common stressor or loss, such as the death of a loved one, is not a mental disorder. Socially deviant behavior (eg, political, religious, or sexual) and conflicts that are primarily between the individual and society are not mental disorders unless the deviance or conflict results from a dysfunction in the individual, as described above" [13: p. 2].

While the language of DSM-5 attempts clarification, it also further confuses the role of distress in the diagnosis of mental disorders, noting that distress by itself is not an indicator of a mental disorder when its occurrence is common or expected, and further, that non-normal behaviors are not considered disorders unless dysfunction occurs as a result. These editorial remarks suggest an important and "usual" role for distress in the diagnostic process, but do not assume it as a requirement.

The evolution of ICD's position on distress shows a somewhat similar development. The clinical descriptions and diagnostic guidelines for ICD-10's mental and behavioral disorders—approved some 30 years ago in 1990—defined a mental disorder as "a clinically recognizable set of symptoms or behaviors associated *in most cases with distress* (italics added) and with interference with personal functions."[41] The ICD-11, which is now in effect, describes mental disorders as "syndromes characterized by clinically significant disturbance in an individual's cognition, emotional regulation, or behavior that reflects a dysfunction in the psychological, biological, or developmental processes that underlie mental and behavioral functioning."[5] Notable is the omission of distress in this more recent definition of mental and behavioral disorders (although it may have been assumed with the language of "disturbance. . .in emotional regulation). In contrast—and as noted previously—ICD-11 explicitly states that in order to be considered a *sexual dysfunction*, the problem should be associated with "significant clinical distress."[23]

While DSM and ICD show significant overlap regarding the presumed role of distress in the description and diagnosis of mental disorders, these 2 systems were developed and evolved in different contexts and with somewhat different end-group focus. DSM was developed for psychiatrists and other mental health workers, whereas ICD was developed for general practitioners and various specialists with the goal of balancing its 5 uses: clinical; research; teaching and training; health statistics; and public health.[40] Nevertheless, distress—as a psychological variable related to mental health—would seem an appropriate element for inclusion in the diagnosis of any mental disorder.

DISCUSSION

Herein we review arguments for and against inclusion of distress in the diagnosis of mental disorders in general, and the impact of adopting one or the other tack. We then return to a

discussion that includes empirical evidence regarding the role that distress might play in the diagnosis and understanding of PE.

Arguments for Inclusion or Exclusion of Distress in Mental Disorders

Two recent papers provide in-depth discussion of the role of distress in the diagnostic criteria of mental disorders. In 2019, Amoretti and Lalumera[39] advocated for the removal of "harm" as a criterion for general mental health diagnosis, with a provision that it might be included only when doing so would be helpful and, in such cases, only if this assessment is unpacked and clarified. As a counterpoint, in 2021, Biturajac and Jurjako[37] advocated for returning the notion of harm as a required criterion, both because it might help distinguish between "pathological" and "nonpathological" for those with mild-to-moderate dysfunction and because it might help prevent the potential misuse of psychiatric/clinical authority.

Arguing for Exclusion

Regarding exclusion, Amoretti and Lalumera[39] point out that DSM-5 has downgraded the harm requirement from being a necessary condition to a frequent or typical characteristic, from being a prescription to being a description. They argue that this downgrading *has not gone far enough* for most mental conditions that include components of harm (defined as distress or disability), noting that the imprecision in defining distress leads to great variation in interpretation. The common use of additional terms such as worry, anxiety, and preoccupation only adds to the confusion and does little to enhance the assessment of disorder intensity or to distinguish between normal vs pathological levels. Further, inclusion of the distress/harm criterion could lead to incorrect diagnostic outcomes, for example, an individual that over-responds with bother/distress to a somewhat minor impairment might fall into a dysfunctional category—that is, the patient's diagnosis ends up relying too heavily on the bother/distress response relative to the magnitude of the actual dysfunction.

Regarding the disability component of harm, Amoretti and Lalumera[39] point out that disability "is a relational context-dependent condition" (p. 329) where, to a large extent, characteristics of the immediate environment and access to needed resources make a significant difference in whether the person's functioning is abled or dis-abled. The authors argue for the exclusion of both these harm elements (distress and disability), making the point that diagnoses should be based only on dysfunction whereas decisions about treatment *may consider distress and disability* and other factors. As an example, they cite Persistent Complex Bereavement Disorder (PCBD) (Prolonged Grief Disorder in ICD-11[5]), where harm is captured by a list of 8 options and where at least two of them must be present for at least one month for a positive diagnosis. The approach taken by Amoretti and Lalumera[39] contends that the development and use of individual diagnosis-specific risk factors would be more productive in the diagnostic process than focusing on imprecise and poorly defined constructs such as distress and disability. Using PCBD as an illustration, a number of risk factors such as being a first-degree relationship to the deceased, separation anxiety in childhood, controlling parents, abuse by or death of parents during childhood, a poorly-functioning marriage or insecure attachment style prior to widowhood, emotional dependency on the deceased, lack of preparation for the death, and in-hospital death of the loved one have been associated with a higher probability of developing PCBD as well as greater adverse impact on affect and/or functioning.[42]

Nevertheless, Amoretti and Lalumera[39] also argue that there are diagnoses for which inclusion of the harm criteria might be helpful. In such cases, they pose 2 critical questions: "(i) What is the role of the harm requirement as a diagnostic criterion, and (ii) With respect to whom by whom, and how should distress and disability be judged and evaluated?" The first question relates to whether there are relevant biological markers and clinically useful measurements of severity for the particular diagnosis. If these are well-developed, then the addition of harm criteria is not likely to add to the diagnostic accuracy. If severity cannot be easily assessed by dysfunction and therefore harm *is* included, then what refinements in assessing distress or disability would be helpful? Either way, a separation of assigning a mental health diagnosis based solely on dysfunction would be correlated with, though not identical to, decisions about treatment, the latter often being influenced by the presence of distress. Their second question relates to who is best suited to evaluate harm (distress or disability). The patient? The physician? Most DSM diagnoses have the patient or client make this determination, though this strategy is not universal. For example, hoarding disorder or paraphilic disorder may not distress the individual but may cause great distress to others immediately affected by it.

Arguing for Inclusion

The paper by Biturajac and Jurjako,[37] written as a counterpoint to Amoretti and Lalumera,[39] argues for the return of the DSM-IV "hybrid" approach that requires the assessment of harm in conjunction with determination of dysfunction in order to make a diagnosis. Biturajac and Jurjako[37] offer 6 arguments in support of this recommendation. Their first argument is that the hybrid model (harm + dysfunction) better assesses the impact on the person's life while providing additional justification for treatment and protections of the population. Their second is that eliminating the harm component would not necessarily lessen diagnostic ambiguity; in other words, the inclusion of harm can help determine a diagnosis in cases that are borderline, where the functional impairment is not clear. Separately, they believe that inclusion of the harm dimension is critically important for determining the need for psychiatric treatment. Their third argument is that inclusion of distress or disability helps in the determination of allocation of resources and in treatment focus, that is, medication vs treatment by therapy or other means. Their fourth

argument is that inclusion of harm is not different than medical diagnoses in general, where both the cause of the disease and its symptoms are commonly considered as part of the diagnosis. Their fifth argument is that disturbances of dysfunction focus on explanation, inferences, developing treatments, etc., while disturbances of harm emphasize the lived human experience and directs attention to remediation and prevention. The final argument is that the past benefits of the hybrid model in preventing the societal misuse of psychiatry (eg, use of psychosurgery as a means of patient control) would be weakened by the removal of harm. At times the focus on the essentiality of dysfunction provides important safeguards while at other times, the requirement for harm provides these safeguards.

The Larger Impact of Diagnostic Criteria, including the Role of Distress, on Mental Health Issues

How a dysfunction or disease is defined matters greatly, as much is at stake. The report from the ICD mental and behavioral advisory group wrote "This definition of mental disorders sets the boundaries for what is being classified, and has enormous consequences for public health action, for governments, for health systems, and for research. For example, how mental disorders are defined affects epidemiological estimates of their prevalence, the legal protections available to people affected by them, the structure, functioning, and payment mechanisms for mental health service systems, and evaluation of the outcomes of mental health interventions." Indeed, Amoretti and Lalumera[39]—whose stance is against the inclusion of distress in diagnoses—do concede the historical benefit of inclusion of distress and disability in diagnostic criteria, as their inclusion has had a generally favorable impact on the public perception of various disorders and, equally important, the allocation of governmental and insurance resources for the treatment of nonlethal diseases.

Thus, it is important to recognize that diagnostic systems are both philosophically and culturally embedded and have a very real impact on both the provision of resources and access to treatment. At one end of the philosophical continuum are the naturalists who view mental illness as reducible to a biological dysfunction. Naturalists typically advocate for dysfunction-only diagnostics and so would argue against distress as a criterion. At the other end of the continuum are normativists who hold that mental disorders are heavily value-laden—involving dimensions related to treatability and advocacy for resources—and therefore contending that distress ought to be part of the diagnostic process. Between these 2 views are hybrid theorists who advocate for inclusion of both dimensions. The past 5 decades have seen discussions and decisions on the tensions between the naturalist and normativist positions play out differently in relation to harm inclusion in the diagnostic process. For example, there is uniform agreement that the advocacy and desire of the 1973 nomenclature committee of the American Psychiatric Association to depathologize homosexuality led to the twin considerations of functionality/dysfunctionality *and* distress, which first appeared in DSM-III.[26] Specifically, it was the inclusion of the (lack of) distress element (not present in DSM-II) that enabled the removal of homosexuality from the list of mental disorders. In subsequent years, the diagnostic codes of sexual orientation disturbance and ego-dystonic homosexuality that initially replaced homosexuality were then dropped entirely.

ICD has provided a creative approach to addressing the tensions between dysfunctionality and harm (distress and disability). ICD and its companion effort, the International Classification of Functioning, Disability, and Health (ICF), were co-created to disentangle the diagnostic aspect from the functional impact of mental disorders.[41,43] ICD focuses on classification of disorders or health conditions while ICF focuses on describing the functional consequences, components, or correlates that may be affected by a disorder or health condition (such as harm/distress or harm/disability). This disentanglement is a core change from ICD-10. To this end, Ustun and Kennedy[44] argued that "no functioning or disability should appear as part of the threshold of the diagnosis. . .A separate rating of the disorder (ie, mild, moderate, or severe) after a diagnosis has been made, would rely on an assessment of the development of the disease, its spread, continuity or any measure independent of disability parameters, so as to avoid co-linearity."[41] The ICD-11 Advisory Group assumed a more moderate stance, arguing that in mental and behavioral diagnoses that do not have sufficient direct indicators of the disorder, referring to specific types of functional impairment as thresholds for separating disorder from nondisorder might then become helpful.

Circling Back to the Role of Distress in the Diagnosis of PE

The foregoing discussion, then, raises the critical question regarding the role of distress in defining and diagnosing PE. Does bother/distress add to the accuracy of a PE diagnosis? Does bother/distress add to the currently used direct indicators of lack of ejaculatory control and short EL? Should inclusion of bother/distress for a PE diagnosis not be needed, would inclusion for the purposes of treatment planning and evaluation remain a central but separate priority (ala ICD vs ICF)?

In this section, we briefly review the empirical evidence supporting a role for bother/distress in a PE diagnosis, then return to the issue of whether the theoretical arguments presented above, or the empirical data thus far available, are sufficiently strong to maintain its status quo as a diagnostic requirement or, alternatively, to either alter it, develop a substitute, or eliminate it.

Empirical Support for the Role of Distress in a PE Diagnosis

The negative consequences (bother/distress/harm) of PE symptomology are presumed to drive treatment-seeking behavior in the patient and/or couple[45,46]: obviously, men or couples not experiencing bother/distress would be less prone to seek

treatment. At the same time, these negative consequences (eg, bother/distress) are sometimes difficult to operationalize and (perhaps due to this) are far from universal among men having short ELs or a lack of ejaculatory control. For example, initial research (eg, 1990s − 2000) indicated that "personal distress" was reported in (only) about 45%−65% of men with short ELs.[11,12,47−50] Furthermore, when terminology was broadened to include other characterizations such as "bother, concern, frustration, or feeling guilt," still only about 70% of men demonstrating PE characteristics (eg, lack of ejaculatory control) endorsed moderate-to-very high "bother/distress" related to their condition.[17,18] Thus, a significant portion of men with PE symptomology are "distress-free," indicating that the role for bother/distress in defining and diagnosing PE is far less obvious than for the other 2 criteria, ejaculatory control and EL. What remains unresolved is the reason behind this apparent lack of distress in some men: whether the assessment of bother/distress is inadequate, whether men/couples may have adapted their sexual repertoire so as to attenuate penile stimulation; whether some men with PE symptoms have a lower vested interest in sex with their partner and thus are not distressed; whether the satisfaction of the partner is of little importance to some (highly self-centered) men[18]; and, along these same lines, whether for some men with PE, the short EL is distressing primarily (or only) to the partner. Whether bother/distress is considered a requirement for PE could impact PE classification status, affecting not only eligibility for treatment, but also estimated prevalence rates.

Ironically, despite this somewhat ambiguous role for bother/distress, PE-related Patient-Reported Outcomes (PROs)[51−54] tend to place strong emphasis on the bother/distress dimension of PE, with more items assessing this variable than either ejaculatory control or EL. Furthermore, at present, there is no consensus regarding how bother/distress should be operationalized, or "which bother/distress" (eg, self, partner, relationship) should be emphasized and/or assessed: Perusal of the various PE-related PROs clearly reflects this lack of consensus.[20]

In summary, although bother/distress appears to be a characteristic of the majority of men with PE, it does not appear to be *a sine qua non*. And while the reason for its absence in some men with PE symptoms is unclear, at this juncture, what *is* clear is that men lacking ejaculatory control with short ELs, but who are distress-free would not qualify for a PE diagnosis under the current guidelines (DSM, AUA, ISSM, EUA, ICD-11). At the same time, men who are strongly distressed by their condition—based, say, on PE-related PRO assessment—could qualify for a PE diagnosis even in the absence of significant short-EL or lack-of-control symptomology.[9] Perhaps most relevant to this issue, the empirical companion paper on distress in this journal[55] offers preliminary yet cogent evidence that bother/distress adds little or no meaningful information for improving the accuracy of a PE diagnosis. Specifically, the inclusion of bother/distress improved the accuracy of PE diagnostic classification by only about 0.1% −1.0%, with the range depending on the PE groupings that were used (eg, "definite PE" vs "probable or definite PE"). Furthermore, based on commonality analysis, bother/distress accounted for only 3.6% of the unique variance contributing to a PE diagnosis, compared with the much greater unique variance contributions of ejaculatory control (55%) and EL (27%). Thus, bother/distress was largely redundant with measures assessing the severity of PE symptomology, such that once the magnitude of lack of ejaculatory control and the shortness of EL had been established, information regarding the patient's bother/distress level generally lacked further diagnostic utility.

Integration and Context

Given the larger discussion regarding the role of bother/distress in the diagnosis of mental health disorders, we now return to the question: how should bother/distress be viewed within the context of PE? As just noted, findings from the companion paper in this journal align with the perspective of Amoretti and LaLumera,[39] that inclusion of bother/distress—or comparable terms such as worry, preoccupation, guilt, and anxiety—does little to enhance assessment of intensity, to distinguish between normal vs pathological levels of dysfunction, or to lower the error rate in PE classifications. This concern is intensified by the fact that current definitions of PE—although all include bother/distress as a criterion—neither specify an operationalization of the bother/distress construct, nor recommend items for assessment, nor recommend cut-off levels that should be considered for those items. Further, as mentioned above, the inclusion of bother/distress, as currently embedded in DSM and ICD, has the potential to increase false positive diagnoses, for example, for individuals with borderline latency and control problems but who express disproportionately large distress. As a large part of the purpose of diagnostic systems such as ICD is to track population health, such errors can have important consequences. In accordance with Amoretti and Lalumera,[39] a better approach than focusing on bother/distress might include assessment of individual diagnosis-specific risk factors. For PE, these might include qualifiers similar to those noted in DSM-5[3] and ICD-11,[5] such as the perceived severity of the PE as determined by the shortness of EL or lack of ejaculatory control, percent of sexual episodes resulting in rapid ejaculation, duration of the PE, generalization to all situations and partners, acquired and/or as a result of a medical condition, and so on.

On the other hand, although research findings provide little support for the inclusion of bother/distress as a requirement for the *diagnosis* of PE, we nevertheless consider its assessment a key part of prognosis, treatment strategy, and assessment of treatment success. Were bother/distress not required as a condition of PE, men with PE symptomology who do not experience harm/distress could still be classified as having PE, assuming they met the criteria regarding the lack of ejaculatory control and short ELs. And as such, they would still have the option of seeking treatment if, for example, the bother/distress was experienced exclusively by the partner, or the bother/distress was intermittent

or specific to particular situations. We therefore differentiate between the value of bother/distress in "diagnosing" PE vs "understanding the PE patient or couple," the latter necessarily including discussion and analysis of possible etiology, duration, generality, and "harm" impact on the man, his partner, and their sexual and overall relationship. Along such lines—and in accordance with Biturajac and Jurjako[37]—we strongly advocate for the relevance of bother/distress (under the larger rubric of "harm") in understanding the PE patient/couple, positing that it could help the clinician distinguish between "troubling" and "nontroubling" PE, information that would be relevant to understanding the man's or couple's experience of the problem, a perspective that appears to underlie Althof's[20] (early-on) advocacy for the inclusion of distress as a syntonic vs dystonic specifier rather than as a diagnostic criterion. This distinction is important, as such information would affect a host of important clinical determinations regarding an optimal treatment strategy, for example, guiding decisions regarding the immediacy and intensity of the treatment, the focus of the treatment (on symptomology, distress, or both), whether components of couples/relationship/marital therapy should be included,[56] whether combined medical and psychosexual therapy might represent an optimal approach,[57] and so on. Indeed, although we see minimal value/need for bother/distress in the diagnosis of PE, we believe its role in understanding the man and the partner's experience, in guiding treatment, and in facilitating treatment success is paramount.

RECOMMENDATION AND CONCLUSION

In summary, we posit that assessment and utilization of quality measures of distress and associated risk factors would be beneficial for understanding the lived experiences of the man/couple dealing with PE, for justifying the allocation of resources for treatment, and for determining intervention progress and success. In this regard, however, there is a significant gap in our knowledge: It is not clear how/whether clinicians and researchers currently assess bother/distress for men/couples dealing with PE. For example, do clinicians routinely assess bother/distress as part of a PE diagnosis, or merely assume that presentation at the clinic for sexual help is evidence of distress. If clinicians and researchers do attempt to further assess bother/distress, how do they do so? Through clinical interviews? Through PE-related PROs? Through other instruments? Or through some combination of these?

Bother/distress, as currently assessed through PE-related PROs, is generally based on the man's perceptions of the situation; however, the case can be made that when bother/distress is evaluated, it should include separate reference to the self, the partner, and the relationship, as each may be evaluated and addressed differently. Understanding each of these dimensions may not only guide the focus of treatment, but would also enable tracking of the various dimensions of this construct as intervention strategies—whether biomedical, cognitive/behavioral, interpersonal, or some combination thereof—are implemented.

To offer a starting point, we have enumerated all the items dealing with the negative consequences of PE currently included in four major PE-related PROs[51–54] in Table 2. These items—in our view only marginally related to making an accurate PE diagnosis—could provide a range of validated questions (some in languages other than English) to enable both clinicians and researchers to quantify the level and location of the "harm/distress" component (patient, partner, etc.) of PE. At the same

Table 2. Existing PRO questions and suggested options for assessing distress

Existing Questions from PE-related PROs Assessing Distress
Premature Ejaculation Profile (PEP) (1 not at all to 5 extremely)
How distressed are you by how fast you ejaculate during sexual intercourse?
To what extent does how fast you ejaculate during sexual intercourse cause difficulty in your relationship with your partner? (also used in CHEES)
Premature Ejaculation Diagnostic Tool (PEDT) (0 almost never to 4 almost always)
Do you feel frustrated because of ejaculating before you want to? (also used in CHEES)
How concerned are you that your time to ejaculation leaves your partner sexually unfulfilled?
Index of Premature Ejaculation (IPE) (1 not at all distressed to 5 extremely distressed)*
Over the past four weeks, how distressed (frustrated) were you by how long you lasted before you ejaculated?
Over the past four weeks, how distressed (frustrated) have you been about your control over ejaculation?
Suggested Questions to Assess Bother/Distress (1 not at all to 5 extremely)
Questions about affect
Do you feel frustrated, bothered, upset, distressed, or guilty because of ejaculating before you want to?
To what extent does ejaculating quickly during sexual intercourse cause difficulty in your relationship with your partner?
How concerned are you that your time to ejaculation might upset, bother, or frustrate your partner or leave your partner sexually unfulfilled?
Question about behaviors
Does ejaculating quickly ever lead you to avoid sexual/physical intimacy, or make you anxious about having sex with your partner?

*Note: IPE scale scoring altered to reflect increases in scores to reflect greater distress.

time, expansion of items to include several behavioral options indicating an underlying negative emotional state might also be considered. For example, behaviors such as "avoidance of intimacy," "reluctance to engage in sex," and "difficulty discussing the issue with one's partner" may enable further insight into the effect of the PE on the man and his partner. Although the suggested item re-wordings and inclusions in Table 2 have not been validated, they offer both a face-valid and content-valid approach to assessing men with PE that aligns more strongly with the language/descriptions currently included in the PE definitions.

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