



Sexual Medicine

Development and Validation of a Premature Ejaculation Diagnostic Tool

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Abstract

Objectives: Diagnosis of premature ejaculation (PE) for clinical trial purposes has typically relied on intravaginal ejaculation latency time (IELT) for entry, but this parameter does not capture the multidimensional nature of PE. Therefore, the aim was to develop a brief, multidimensional, psychometrically validated instrument for diagnosing PE status.

Methods: The questionnaire development involved three stages: (1) Five focus groups and six individual interviews were conducted to develop the content; (2) psychometric validation using three different groups of men; and (3) generation of a scoring system. For psychometric validation/scoring system development, data was collected from (1) men with PE based on clinician diagnosis, using DSM-IV-TR, who also had IELTs ≤ 2 min ($n = 292$); (2) men self-reporting PE ($n = 309$); and (3) men self-reporting no-PE ($n = 701$).

Standard psychometric analyses were conducted to produce the final questionnaire. Sensitivity/specificity analysis was used to determine an appropriate scoring system.

Results: The qualitative research identified 9 items to capture the essence of DSM-IV-TR PE classification. The psychometric validation resulted in a 5-item, unidimensional, measure, which captures the essence of DSM-IV-TR: control, frequency, minimal stimulation, distress, and interpersonal difficulty. Sensitivity/specificity analyses suggested a score of ≤ 8 indicated no-PE, 9 and 10 probable PE, and ≥ 11 PE.

Conclusions: The development and validation of this new PE diagnostic tool has resulted in a new, user-friendly, and brief self-report questionnaire for use in clinical trials to diagnose PE.

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1. Introduction

Premature ejaculation (PE) is the most common ejaculatory disorder. Epidemiologic studies indicate that PE has an estimated prevalence of approximately 16–38% across all age groups of the male population [1].

Although defined in several ways, the most widely accepted definition is *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (DSM-IV-TR)* [2], which uses vague terms such as “minimal sexual stimulation,” “before the person wishes it,” and “causes marked distress or interpersonal difficulty.”

Traditionally, intravaginal ejaculation latency time (IELT) has served in clinical trials as an operational marker for DSM-IV-TR criteria. Frequently, the IELT inclusion criterion has been set at 1 or 2 min. Waldinger et al [3] found, in their meta-analysis of PE drug treatment studies, of 41 studies that used a time-based operational definition 30 used 1 or 2 min as the PE definition. Three minutes or less was used in 8 studies, and 30 s, 4 min, and 5 min were used in 1 study each. However, the 1- or 2-min cut point does not fit all. There are men who would still consider themselves premature with an IELT of 3, 4, or even 5 min, as evidenced by Patrick et al's [4] study. Conversely, there are men who do not consider they have PE with IELTs of 1 or 2 min. The International Consultation on Sexual Dysfunctions ejaculation committee members [5,6] suggested that IELT, control, and distress elements all be considered when diagnosing PE, because PE is not simply a function of time; men also complain of lack of control, sexual dissatisfaction, and/or concern about partner dissatisfaction.

Since diagnosis seems to warrant more than just an assessment of time, it was proposed that a self-report measure that encompasses the essence of DSM-IV-TR be developed.

2. Part 1: Pilot tool development

2.1. Method

2.1.1. Study design

Five focus groups (6–7 men each) and six individual interviews were convened with men who self-reported having PE, or who were currently receiving treatment for their PE. The focus groups were conducted in the United States and Germany. Because we were advised against use of a focus group model in Spain, we conducted individual interviews. Focus groups and interviews were

conducted in subjects' native language. These countries were chosen to give a range of cultural experience. Following this qualitative data collection, a panel of five clinical experts was then convened in July 2004 to add input to the process. The panel members were chosen on the basis of geographic distribution (France, Australia, United States), years of experience in diagnosing PE, and to multidisciplinary variability (sex therapist, primary care provider, urologist, experimental psychologist).

2.1.2. Study population

2.1.2.1. *Focus groups and individual interviews.* Recruitment was based on a diagnosis by a physician or by self-report. Participation in interviews conducted in Spain was based solely on a man's self-report of experiencing PE.

The average age of the men was 44.34 yr (standard deviation = 11.44). Regardless of marital status, a current relationship was required for participation; most (62%) were married. Average years spent in their current relationship was just under 10. Nearly 40% had middle-class incomes, 65% had at least some college education, and the group was 72% Caucasian. The average number of years with PE was just under 8, and the men had either lifelong or acquired PE.

2.1.3. Study procedure

2.1.3.1. *Focus groups/individual interviews/clinical expert panel.* After informed consent was obtained, participants were asked 16 open-ended questions about their experience with PE and its impact on their relationship. Example questions included: How would you describe PE? How do you think your experience of ejaculation compares with what you might expect to be a “normal” or usual sexual experience? How does having PE make you feel (distressed, angry, frustrated, disappointed, annoyed, bothered)? Is “control” an issue for you?

For the expert panel, clinical experts were asked to present and discuss their clinical experience with PE, focusing in particular on the process of diagnosis.

2.1.4. Results

The results from the qualitative work and expert panel are summarised below:

- When men described their symptoms, they talked about problems with *timing* of ejaculation, rather than lasting a certain amount of time.
- They generally rejected the concept that PE could be defined by absolute time to ejaculation, particularly as their usual sexual practice tended

to incorporate other sexual activities. It was unusual for many of them to have a period of uninterrupted intercourse culminating in ejaculation.

- They identified control over ejaculation as being important, but this tended to be discussed as a better degree of continence, rather than absolute control, which they did not see as realistic.
- Most men did not identify with the word “distress” to describe the emotional impact of their PE. Rather, the word “frustration” seemed to be the most appropriate and widely used descriptor.

Components men wanted to see incorporated into a diagnostic measure were concepts such as:

- Ejaculating before you wish to
- Inability to delay ejaculation
- Inability to control ejaculation

The 9-item PEDT was tested for understanding in two additional focus groups (United States and Germany). There were no issues with the content; a definition of PE was added for clarity. The version in [Appendix A](#) was taken forward for validation.

3. Part 2: validation

3.1. Method

3.1.1. Study design

We recruited a cohort of men with PE defined according to DSM-IV-TR and known IELT of ≤ 2 min in 70% of coital attempts. These men (all from the US) were asked to use a stopwatch to time IELT over a 4-wk duration (time-defined population).

The self-reported population (self-reported PE and self-reported no-PE) was recruited by using

Harris Interactive Service Bureau (HISB), a US Web-based survey system. The incentive for being on this panel was a system of points awarded for surveys completed, which could then be redeemed at an online store.

3.1.2. Study populations

3.1.2.1. *Time-defined population.* In total, 292 men were recruited, with known IELTs of \leq than 2 min in $>70\%$ of coital attempts.

3.1.2.2. *Self-reported population.* We categorized as “self-reported PE” ($n = 309$) subjects who responded with “probably yes” or “definitely yes” to the following question: “Premature ejaculation is a term commonly used to refer to the condition when a man ejaculates before he and/or his partner wants him to. Given this definition, do you think you suffer from premature ejaculation?” Also, these men had to have partners who did not have any sexual problems.

Subjects who responded with either “definitely not” or “not sure” were categorized as “self-reported no-PE” ($n = 701$).

3.1.3. Demographics

The demographics for each of the cohorts can be seen in [Table 1](#).

3.1.4. Study procedure

3.1.4.1. *Time-defined population.* Men were recruited by advertisement and were screened with the use of the following criteria: experienced PE for at least 10 yr, aged 18–65 yr, in a stable relationship for at least the last 6 mo, fulfilled DSM-IV-TR criteria for PE, and reported no erectile dysfunction (according to the International Index of Erectile Function [7]). Men meeting the initial screening criteria completed a consent form, provided initial questionnaire

Table 1 – Demographics for the time-defined, self-reported PE, and self-reported no-PE cohorts

Population	Time-defined ($n = 292$)	Self-reported PE ($n = 309$)	Self-reported no-PE ($n = 701$)
Age (yr)			
18–41	72%	33%	43%
42–65	28%	67%	57%
Relationship			
Yes	100% ^a	74%	70%
>1 year	76%	94%	91%
IELT			
Mean (SE)	66 s (1.78)	279.4 s (19.22)	490.9 s (36.26)
Median	65 s	180	300

PE = premature ejaculation; IELT = intravaginal ejaculation latency time; SE = standard error.

^a All men in the time-defined population had to be in a stable relationship for at least 6 mo.

information (demographics and PEDT), and were given an explanation of the 4-wk diary process. The men were then given an electronic diary with embedded stopwatch to take home to record IELTs and confirm an IELT of ≤ 2 min in 70% of coital attempts. Each subject was given the option of either he or his partner operating the stopwatch. Whichever partner timed the ejaculation on the first occasion continued to do so throughout the course of the 4-wk study. Two weeks after subjects were enrolled, they received a second PEDT by mail, along with a self-addressed stamped envelope, to complete and return (for assessing retest reliability). At the end of the 4-wk period, participants returned and completed a further PEDT survey.

3.1.4.2. Self-reported population. A survey asking screening criteria similar to those above was sent out to a general population of men; it also contained the PEDT and a question about PE status (as given above) to confirm the subjects' belief that they ejaculated prematurely or did not ejaculate prematurely. IELT information was not captured for this group because it was meant to be broad and not constrained by an IELT cut point.

3.1.5. Statistical analyses

3.1.5.1. Psychometric analyses. Various analyses were carried out to identify items to include in the final PEDT (Table 2).

Once the final items for the tool were selected, the resulting tool was then checked to see that internal consistency, test-retest reliability, and known-groups validity still applied.

The psychometric tests listed in Table 2 were also performed on the self-reported PE population to explore whether a similar set of items was selected.

Before agreeing on the final content of the tool, the psychometric test results were reviewed by three experts (Drs S. Althof [S.A.], F. Giuliano [F.G.], M. Perelman [M.P.]).

3.2. Results

3.2.1. Performance of individual items

Item-to-item correlations were acceptable. The correlation coefficient between items 9 and 4, 5, 7, and 8 was greater than the predefined critical value of 0.70 (see Appendix A for item content). The overall Cronbach alpha for the 9-items was 0.86. Test-retest reliability was good (0.82), and all items statistically significantly discriminated between those with PE and those without PE.

One factor was retained (Eigen value of the first factor: 4.03), which explained 95% of the variance and factor loadings >0.4 ; loadings ranged between 0.41 (item 6) and 0.88 (item 9).

3.2.2. Reduction of the items

Following a discussion with the three experts, items 1, 2, 3, 4, and 8 were retained (see Appendix A). Although the known-groups validity for each item was very good, item 6 performed less well at discriminating between the two populations than the other eight items. Item 9 failed the prespecified criterion of an item-to-item correlation of <0.70 with item 7. It was also highly correlated with items 4, 5, and 8. Item 7 was highly correlated with items 4 and 5. In addition, there was a high correlation between items 4 and 5. Items 7 and 9 were deemed redundant and were removed. Similarly, there was some redundancy between items 4 and 5; item 5 was removed.

In terms of clinical face validity, the five selected items best summarized the essence of DSM-IV-TR. Items 1-3 covered the concept of control, but 2 and 3 also addressed frequency and minimal sexual stimulation, respectively. Item 4 addressed the concept of distress, and item 8 covered the issue of interpersonal difficulty.

3.2.3. Psychometrics of the 5-item PEDT

Factor analysis of the 5 items retained the one-factor solution.

The reliability of the 5-item version was good (Cronbach alpha = 0.71; test-retest reliability = 0.73). Difference in mean score between the time-defined population and self-reported no-PE group was

Table 2 – Psychometric analyses

Factor analysis	Common factor analysis with Promax rotation [8]. A priori criteria for domain identification and item retention were (1) Eigen values >1.0 ; (2) items with factor loadings >0.4
Item-to-item correlation	Pearson correlation coefficient was used; correlation coefficients >0.70 indicate redundancy.
Reliability	
Internal consistency	Cronbach alpha score 0.7 is considered good internal consistency.
Test-retest reliability	Intraclass correlation coefficient (ICC): the minimal acceptable level was defined as 0.70.
Validity	
Known-groups validity	Independent t test to determine whether items could discriminate between those with PE and those without PE.
PE = premature ejaculation.	

highly statistically significantly different (mean difference = 11.8; 95% confidence interval, 11.3–12.2); $p < 0.0001$).

The psychometrics from the self-reported PE population confirmed that items 1, 2, 3, 4, and 8 were the best items to retain.

The final version of the tool ([Appendix B](#)) was taken forward for assessment of the most appropriate cut score to indicate presence or absence of PE.

4. Part 3: scoring system

4.1. Method

4.1.1. Sample size

The number of men in the time-defined population was determined by a general formula for sample size estimation when constructing a two-sided confidence interval for single test accuracy on sensitivity [9].

The minimum number of subjects required for each cohort (PE and no-PE) was 246.

4.1.2. Sensitivity/specificity analysis

Sensitivity was defined as the proportion of subjects with the disorder who were diagnosed as having the disorder (true positive rate); specificity was defined as the proportion of subjects without the disorder who were diagnosed as not having the disorder (true negative rate).

The time-defined population was the source of information for subjects “with” the disorder. The no-PE population was used as the group “without” the disorder. The scoring system for the diagnostic tool was derived from the point at which the sensitivity/specificity ratio was closest to unity (this approach maximized both sensitivity and specificity).

The primary analysis was conducted on the time-defined PE population and the self-reported no-PE population. Secondary analysis used the self-reported PE population and the self-reported no-PE population.

4.2. Results

4.2.1. Primary analysis: time-defined PE versus self-reported no-PE (definitely no/not sure)

The diagnostic tool discriminated between the two cohorts (sample size: 294 vs. 701, respectively) extremely well, suggesting that both groups were answering the questions very differently. When sensitivity/specificity were maximised, a score

between 10 and 11 was the best predictor of PE status.

4.2.2. Secondary analysis: self-reported PE (definitely yes and probably yes) versus self-reported no-PE (definitely no and not sure)

There was a good fit between the two self-reported cohorts (sample size: 309 vs. 701, respectively). A score of ≤ 7 indicated no-PE and ≥ 8 indicated PE.

4.2.3. Additional exploratory analyses

The time-defined versus self-reported no-PE (“definitely no” only, $n = 474$) had the strongest fit; the two cohorts clearly responded very differently. The sensitivity/specificity analysis produced a score of ≤ 8 for no-PE and ≥ 9 for PE.

The final analysis used men who self-reported PE as “definitely yes” only ($n = 68$) versus the full data set of men who self-reported no-PE (“definitely no” and “not sure”). A score of ≤ 9 indicated no PE and ≥ 10 indicated PE.

The data were reviewed and discussed with the experts. The scoring system was set at ≥ 11 to suggest a diagnosis of PE. Since the predicted cut point between PE and no-PE status went as low as ≥ 8 , and the “not sure” group would have a score between 9 and 10, it was agreed that “probable PE” should be defined in this range; any man scoring a 9 or 10 would necessitate further assessment. A score below 9 would indicate low likelihood of PE.

5. Discussion

A literature search revealed only one tool that purported to discriminate PE from non-PE: Chinese Index of Premature Ejaculation [10]. However, it was developed as an efficacy measure and did not specifically address the DSM-IV-TR criteria. This study’s objective was to develop a validated, short tool using DSM-IV-TR classification criteria to diagnose PE. While individual clinicians rely on the DSM-IV-TR criteria, there is wide variability in application. The PEDT was developed to standardise the diagnosis of PE in future clinical trials and was designed to capture the main elements of DSM-IV-TR: control, frequency, minimal sexual stimulation, distress, and interpersonal difficulty. These elements mirrored the patient concerns arising in focus groups and individual interviews. In fact, from the focus groups, it was clear that PE’s impact on men was primarily one of lack of control and emotional impact on the man and his partner. These concerns accounted for the large number of emotional concepts incorporated into the draft tool

to determine which emotional descriptor was relevant to most men (frustration, lack of confidence, dissatisfaction, and disappointment). Feelings of lack of confidence were previously shown to be the most common complaint associated with PE [11]. However, in attempting to capture the essence of distress it was the word "frustration" that most resonated with the men interviewed. Some men felt that "distress" was more a female-oriented concept, and others believed this term was too strong for what they felt about their condition. These same views had been previously cited by men in other focus groups during the development of an outcome measure: Index of Premature Ejaculation [12]; "distress" is now defined as "frustration" in this measure. The psychometric analyses confirmed this item best captured men's distress/emotional impact of experiencing PE. Also, Symonds et al [11] highlighted that men were aware of the impact of PE on their relationship, showing that such an item in any diagnostic tool is very relevant.

Overall, the final combination of items showed excellent psychometric properties supporting its validity and reliability. The subsequent sensitivity/specificity analyses suggested a consistent cut score of ≤ 8 "no PE," 9 and 10 "probable PE," and ≥ 11 "PE." This result was obtained despite the fact that the self-reported PE men were older than the time-defined PE men and was collected via an Internet panel. Using an Internet system to select the self-reported PE population could have resulted in a quite dissimilar group; however, educational background, ethnicity, and relationship history were all similar. The difference observed in IELTs was expected as Waldinger et al's [13] earlier research showed self-reported estimates of IELT tend to be higher than those recorded using a stopwatch. While age difference was not expected, the younger age may have been driven by the fact that men had to take home an

electronic diary to record IELT, and that younger men may be more confident in using electronics. However, the wide spectrum of ages and the fact that the time-defined/self-reported PE populations had very different IELTs strengthen the PEDT's applicability across a broad group of men with PE.

The PEDT will help overcome the variability of application of DSM-IV-TR criteria and allow clinicians to have a sense of assurance that a patient merits diagnosis and treatment. The clinician, whose patient scores "probable PE," will be appropriately prompted to investigate further to determine actual PE status.

In the absence of a gold standard for diagnosing PE and evidence of variation in the relationship between absolute time and PE, the next step for testing the PEDT's validity will be to test it against expert clinician diagnosis. This step will allow consideration of any danger of "overdiagnosis" by the tool. Since we know that IELT is culturally dependent [14], the PEDT's cross-cultural applicability must also be researched further.

6. Conclusions

The PEDT is a short, psychometrically validated measure that can be easily administered to facilitate the diagnosis of PE.

Conflicts of interest

Tara Symonds, Kathryn May, Lucy Abraham, Anna Crossland, and Mark Morris are all Pfizer Inc employees.

Michael Perelman, Stanley Althof, and François Giuliano are paid consultants to Pfizer Inc.

Mona Martin has no conflict of interest.

Appendix A. Draft Diagnostic Tool

Tool for Assessing Premature Ejaculation

This is a questionnaire to help identify men who may have a problem with ejaculating too soon during sexual activity. Even if you do not have difficulties, please answer all the questions.

- Please mark the box that best represents your answer for each of the questions below.
- Please mark only one box for each question.
- Remember there are no right or wrong answers to these questions.
- While your experiences may change from time to time what we're interested in here is your general experience with intercourse.

Definition:

Ejaculation here means from the time of penetration (when your penis enters your partner) until ejaculation (release of semen).

	Not difficult at all	Somewhat difficult	Moderately difficult	Very difficult	Extremely difficult
1. How difficult is it for you to delay ejaculation?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4

	Almost never or never 0%	Less than half the time 25%	About half the time 50%	More than half the time 75%	Almost always or always 100%
2. Do you ejaculate before you want to?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
3. Do you ejaculate with very little stimulation?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4

	Not at all	Slightly	Moderately	Very	Extremely
4. Do you feel frustrated because of ejaculating before you want to?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
5. Do you feel your sexual confidence is affected by your time to ejaculation?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
6. Do you feel you have control over the timing of your ejaculation?	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
7. Does your time to ejaculation leave you feeling disappointed with your sexual life?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
8. How concerned are you that your time to ejaculation leaves your partner sexually unfulfilled?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
9. Does your time to ejaculation leave you feeling dissatisfied with your sexual life?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4

Appendix B. Final PE Diagnostic Tool

Tool for Assessing Premature Ejaculation

This is a questionnaire to help identify men who may have a problem with ejaculating too soon during sexual activity. Even if you do not have difficulties, please answer all the questions.

- Please mark the box that best represents your answer for each of the questions below.
- Please mark only one box for each question.
- Remember there are no right or wrong answers to these questions.
- While your experiences may change from time to time, what we're interested in here is your general experience with intercourse.

Definition:

Ejaculation here refers to ejaculation (release of semen) after penetration (when your penis enters your partner)

	Not difficult at all	Somewhat difficult	Moderately difficult	Very difficult	Extremely difficult
1. How difficult is it for you to delay ejaculation?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4

	Almost never or never 0%	Less than half the time 25%	About half the time 50%	More than half the time 75%	Almost always or always 100%
2. Do you ejaculate before you want to?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4

3. Do you ejaculate with very little stimulation?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
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	Not at all	Slightly	Moderately	Very	Extremely
4. Do you feel frustrated because of ejaculating before you want to?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
5. How concerned are you that your time to ejaculation leaves your partner sexually unfulfilled?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4

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