

Development and Validation of a New Questionnaire to Assess Sexual Satisfaction, Control, and Distress Associated with Premature Ejaculation

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ABSTRACT

Introduction. No validated questionnaires to assess the subjective aspects of premature ejaculation (PE) are currently in use. Clinical trials have generally only considered time, measured by ejaculatory latency, as an indicator of efficacy, but ejaculatory control, sexual satisfaction, and distress are important aspects of PE, which impact both the patient and his partner. The objective of this study was to develop and validate a new questionnaire to measure the overall experience of PE.

Methods. The questionnaire was developed using four stages: item pool development, initial psychometric analyses, patient interviews, and final psychometric analyses.

Results. An item pool of 17 was generated and reduced to 10 items through the initial psychometric analyses. Patient interviews did not require addition of further items and resulted in only minor modifications to item wording for clarity. Final psychometric analyses of the 10-item measure confirmed a three-factor solution: sexual satisfaction, control, and distress. Reliability was good, both internal consistency and test-retest reliability. Convergent validity using intravaginal ejaculatory latency time was excellent: control domain (0.75), sexual satisfaction domain (0.60), and distress domain (0.68). Known-groups validity was very good, all domain mean scores being statistically significantly worse in men with PE compared with the men reporting no PE problems.

Conclusion. The Index of Premature Ejaculation is a reliable and valid questionnaire for the assessment of control over ejaculation, satisfaction with sex life, and distress in men with PE. This tool has the potential to add value to interpretations of improvements in ejaculation latency resulting from new treatments of PE. **Althof S, Rosen R, Symonds T, Mundayat R, May K, and Abraham L. Development and validation of a new questionnaire to assess sexual satisfaction, control, and distress associated with premature ejaculation. J Sex Med 2006;3:465–475.**

Key Words. Psychological Assessment of Sexual Dysfunction; Premature Ejaculation; Questionnaire

Introduction

The evaluation and treatment of premature ejaculation (PE) has lagged behind the impressive advances realized in the diagnosis and treatment of erectile dysfunction. The tide appears to be turning, with exciting research aimed at understanding the pathophysiology of ejaculatory dysfunction and the early development of innovative oral therapies for this condition.

While there have been attempts to develop valid and reliable questionnaires to measure PE, or the impact of treatment on the patient or partner, for various reasons they have not fully achieved this objective.

The development of new oral therapies for PE has stimulated the need for measurement scales which go beyond ejaculatory latency, referred to as intravaginal ejaculatory latency time (IELT). These questionnaires must be brief and psycho-

metrically sound, as well as able to measure the relevant domains associated with PE. This article reports on the development and validation of such a scale, the Index of Premature Ejaculation (IPE).

Nosological Categories, Prevalence, and Diagnostic Criterion

Premature ejaculation is the most common male sexual disorder. Epidemiological studies indicate that PE has an estimated prevalence of approximately 22–38% across all age groups of the male population [1–3].

Ejaculating prematurely is an embarrassing condition and is associated with increased anxiety [4] and loss of sexual confidence [5]. Increased likelihood of marital problems has also been reported [6,7]. Furthermore, women often feel angry, disappointed, frustrated, and lonely after sexual intercourse with their partner [8].

Premature ejaculation has been defined in several different ways, but the most widely accepted is the definition [9]:

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

Treatment Outcome Variables

Time to ejaculation is considered a primary outcome variable, referred to as IELT, a term coined by Waldinger et al. [10], for clinical trials. However, Rowland [11] suggests that PE has multiple etiologies and should therefore be assessed multidimensionally. He and others [12] have suggested that relevant outcome variables include: (i) IELT; (ii) control over ejaculation; and (iii) sexual satisfaction. Additionally, the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition, text revision (DSM-IV-TR) [9] and the American Urological Association Guidance on the Pharmacological Management of Premature Ejaculation [13] both suggest that distress be part of the multidimensional assessment of PE.

A review of the literature found two questionnaires: Hartmann's [14] PEQUEST (Premature Ejaculation Questionnaire), and Althof & Corty's Pentech Ejaculation Inventory—PEI (not published, 1997) (S Althof and E Corty, personal communication), but neither was taken forward and

validation was not completed. More recently, the Chinese Index of Premature Ejaculation was developed [15]; however, it does not capture the three key domains highlighted above.

Therefore, the authors began development of a self-report questionnaire that assesses self-perceived control over ejaculation, sexual satisfaction, and distress.

Questionnaire Development

The questionnaire was developed in four stages and will be reported separately:

- Stage 1, development of the item pool to form the pilot questionnaire.
- Stage 2, initial psychometric analysis.
- Stage 3, qualitative interviews with men with PE.
- Stage 4, further psychometric analyses.

Stage 1: Pilot Questionnaire Development

The item pool was initially generated through discussions with two experienced sex therapists (Professors Althof and Rosen) located in the United States, during July 2000.

Face-to-face interviews with each expert were conducted. The experts discussed their experience of men's complaints in relation to their PE. The experts articulated statements that these men might make in a consultation about their condition. In all, 17 items were formed to address four concepts; these included: (i) distress about PE; (ii) control over ejaculation; (iii) limitations in foreplay; and (iv) sexual satisfaction. See Appendix A for the pilot questionnaire.

Stage 2: Initial Psychometric Analyses

Method

Study Design

Three cohorts were used to assess the psychometric properties of the pilot questionnaire.

Study 1. A *clinical trial* data set of men screened into a study for the treatment of PE. These data were used to carry out the majority of the required psychometric analyses.

Study 2. A *normative data set* (i.e., men who reported no problems with their ejaculatory latency) was also collected, through an independent company (NOP World), to enable known-groups validity data to be generated.

Study 3. A sample to evaluate test–retest reliability was also recruited by an independent company (Health Research Associates Inc.).

Study Populations

Study 1. A cohort of 147 men was recruited. These men had to have lifelong (primary) PE, with an IELT ≤ 2 minutes in 75% of attempts. IELT was confirmed via a 4-week period, in which the subject or his partner used a stopwatch to time ejaculatory latency.

The age range was 18–65 years, with 58.6% aged 18–45 years, and 41.4% aged 46–65 years. The mean age was 42.2 (10.04) years. Average and median IELTs were 1.92 (2.98) minutes and 1.21 minutes, respectively.

Study 2. For determination of known-groups validity, a cohort of men without PE (“normal”) (N = 141) was recruited in the United States.

The age range was the same as for study 1, with 55.8% aged 18–45 years and 44.2% aged 46–65 years. Average and median IELTs were self-reported and much higher (12 [SD 8] and 10 minutes, respectively).

Study 3. Thirty-four men in the United States provided the data for the test–retest analysis. These men all self-reported IELTs of ≤ 2 minutes in 75% of attempts.

Men had either acquired or lifelong PE. The age range was slightly broader for this cohort—18–82 years, but, overall, had a higher proportion of younger men: 18–45: 76%, 46+: 24%, which gave a slightly lower mean age of 39.02 (SD 16.08) years. Average IELT could not be calculated because individual latency times were not collected.

Study Procedure

Study 1. The men were identified for screening and possible entry into the clinical trial through clinics in Australia, Norway, and the Netherlands. These 147 men completed the pilot PE questionnaire, regardless of whether or not they went on to be randomized into the clinical trial.

Study 2. The normative sample was recruited in the United States, through NOP World (July 2001), who surveyed a large sample of men in their database of individuals willing to participate in surveys. In total, 11,000 men were screened, 4,487 (41%) returned the survey, of whom 3,359 (75%) answered “no” to the question “do you sometimes ejaculate before you want to?”. As only approximately 100 respondents were required to generate

sufficient data for the known-groups validity analysis, a random sample of 233 from the 3,359 was sent a further survey containing the questionnaire. A total of 154 were returned for evaluation, with 141 being evaluable, that is, without missing data.

Study 3. Men were asked to complete the questionnaire on two occasions, 7–10 days apart. A global rating of change question was also asked, to determine if a man’s PE had changed for the worse, better, or not at all during that 7- to 10-day period. Analysis of those men who stated “no change” in their symptoms formed the cohort to determine test–retest reliability (N = 25).

Statistical Analyses

Defining Domains and Item Retention

Factor analysis was conducted, to determine which items should be retained and the domain structure of the questionnaire. A priori criteria for domain identification and item retention were:

1. Eigen values >1.0 ;
2. Items with factor loadings >0.4 .

The minimum sample size for the planned factor analysis was 85. This figure is based on the rule-of-thumb that at least five times as many respondents should be used to the number of items in the questionnaire for factor analytic purposes [16].

Item-to-item correlations were assessed. Correlations between 0.4 and 0.7 indicate items that are sufficiently related to form an independent domain.

Validity

Validation techniques to demonstrate the instrument is measuring what we believe it is measuring were ascertained as follows:

1. Convergent validity: The questionnaire correlates with a similar construct. The domains of the questionnaire were correlated with a sexual quality of life questionnaire (SQOL-M [17]) and IELT measurement. The SQOL-M is a general questionnaire, assessing impact of sexual health problems on QOL. It was anticipated that this would correlate highly with sexual satisfaction and distress items and less so with control and foreplay items (more functional domains). A correlation between 0.4 and 0.7 indicates good convergent validity.
2. Known-groups validity: If two groups are known to differ on a given condition then one would expect differing results on a question-

naire targeting information about this condition. In this instance, a comparison of domain scores for men with and without PE was conducted.

Reliability

There are two types of reliability:

1. Internal consistency: These values indicate how reliable the identified questions of a domain are in measuring a given domain. Cronbach's Alpha was used; a score above 0.7 is the minimum level required.
2. Test-retest reliability: This is the main test of the reliability of a questionnaire. In the absence of any change in the group completing the questionnaire, the mean (score) should be consistent over time. An intraclass correlation coefficient was calculated; a score above 0.7 is considered a good indication of the questionnaire's test-retest reliability [18].

Results

Domain Structure

Principal Component Analysis, with varimax rotation, was used to look at the factor structure of the IPE. A four-factor solution was produced, using 14 items of the IPE, and explained 59% of the variance. Further analysis of the items and their relationship to each other indicated that a three-factor solution would be better—the foreplay domain had a ceiling effect and did not discriminate between study 1 and study 2 respondents, hence this domain was discarded. Item 1 was removed from the outset because frequency of intercourse is not generally the concern of men with this condition. Also, it was felt that patterns of changes in sexual intercourse would be better captured using an event log. Item 4 of the control domain did not correlate well with the other items of this domain and was discarded. Item 7 was removed because it also did not discriminate well

between study 1 and study 2 respondents. Item 8 of the sexual satisfaction domain was removed, after discussion with clinical experts, who stated this item was poorly worded and should be discarded to avoid future problems with the item.

The three-domain version of the IPE retains 10 items: sexual satisfaction (9, 13, 14, 15); control over ejaculation (5, 6, 10, 11); and distress about ejaculating prematurely (16, 17). The remaining psychometric analyses looked at the reliability and validity of these three domains.

Validity and Reliability

Details of the validation and reliability analyses can be seen in Table 1. Convergent validity was as expected, as was known-groups validity. Reliability of each domain was clearly demonstrated.

Stage 3: Qualitative Interviews

Method

Patient interviews were conducted to determine whether key concepts or items were missing from the remaining 10 items of the IPE after the psychometric analyses, and to determine whether the items were understandable.

Study Population

Individual interviews were conducted, four in the United Kingdom, and nine in the United States, to ascertain that all concepts relevant to the experience of PE were covered by the questionnaire.

Men were recruited based on the following inclusion criteria:

- Self-reported IELT of ≤ 2 minutes in 75% of attempts.
- A self-report of at least slight distress.
- No erectile problems.

Age range was 21–67 years; mean age was 44.08 years (SD 12.49). Most men (62%) were aged between 47 and 52 years. Six of the men were single, four married, and three divorced.

Table 1 Initial psychometric analyses

Domain	Convergent Validity		Known Groups Validity		Reliability		
	SQL-M	Correlations	Domain mean scores (SD)		P value	Internal consistency	Test-retest reliability
			PE men (n = 149)	Normal men (n = 152)			
Sexual satisfaction	0.65		10.8 (3.40)	15.0 (5.10)	<0.0001	0.82	0.90
Control	0.15		5.5 (2.15)	16.8 (6.53)	<0.0001	0.74	0.90
Distress	0.43		5.0 (1.87)	9.2 (3.49)	<0.0001	0.91	0.70

SQL-M = Sexual quality of life; PE = premature ejaculation; SD = standard deviation.

An additional 30 men were recruited to ensure the questions were understandable (cognitive debrief study). The same entry criteria as above were used.

More of the participating men were married ($N = 16$) than not ($N = 12$), with one being widowed and one being divorced. The age range was from 19 to 75 years, with the largest group being between 35 and 45 years of age (45%).

Study Procedure

The 13 men used to ascertain that all relevant content was covered were recruited via clinician referral (United Kingdom), or through response to an advertisement in the local press (United States). Interviews lasted for approximately 45 minutes and were audiotaped, to allow content analysis after the interview. The men were asked a primary question "What does 'Premature Ejaculation' mean to you?" and this was explored in depth. Additional questions were as follows:

1. Does PE affect the quality of your sexual experience?
2. Choose two of the following words, which most accurately reflects how you feel when you experience PE or think about your condition: annoyance, upsetting, irritation, bothers me, frustration, despair, distress, anger.
3. How would you describe the overall effect that having PE has had on your life?
4. How does your condition affect your general well-being, for example, worry/concerns, fear, and embarrassment?
5. How does having PE affect your self-esteem?
6. How does having PE affect your satisfaction with other general areas of your life, for example, family life, emotional well-being?

The 30 men in the cognitive debrief study were asked to complete the questionnaire, and, while doing so, were asked to speak out aloud their understanding of the question and response options.

After 20 men had been interviewed, their comments were combined for review. Suggested changes were then made and an additional 10 men were interviewed, to ensure that the questionnaire still made sense and items were still relevant.

Results

Based on the responses from the 13 men, to the primary question—"what does PE mean to

you?"—no additional items were added to the questionnaire because the existing 10 items already captured all comments. Time to ejaculation (coming too fast, too quickly) was used to describe PE by a number of the men. This is directly addressed by item 5 of the control domain (see Appendix B), this item being a marker of lack of control over ejaculation. Emotional impact of ejaculating too quickly is measured by item 9. The term "control" was specifically mentioned by a couple of the men, this being assessed in a number of different ways by items 1, 2, and 4. Again, the emotional impact of lack of control over ejaculation is measured by a distress question. The term "distress" was used because the DSM-IV definition of PE indicates that it must cause "marked distress." Over the course of the development of the IPE, it had become apparent that men, in describing the impact of their PE, do not readily use the term "distress." A list of descriptors were, therefore, shown to the interviewees, who were asked to select two words from the list that best defined their experience of PE. All but one chose the "frustration" descriptor, and the next most widely chosen descriptor was "annoyance." The term "distress" was maintained to align with the DSM-IV definition of PE; however, a definition of "distress" was introduced into the questionnaire for clarity. A definition of control was also incorporated into the questionnaire to ensure consistency in understanding. Finally, while the interviewed men did not specifically use the wording of the items in the sexual satisfaction domain, the general nature of these items was felt to cover the essence of the men's dissatisfaction. Men often talked about satisfying their partner as a driving force of their concern, which items 6, 7, and 8 measure. Item 3, ". . . when you had sexual intercourse, how often was it satisfactory for you?" was kept, because it was felt that it is sufficiently general to ascertain the overall impact of taking a drug treatment, that is, the side effect, efficacy, and convenience tradeoff.

Results from the initial 20 cognitive debrief interviews showed that the IPE was well received. The changes that were made, as a result of the interviews, were mainly minor. Frustration seemed to be the more favored term for defining the meaning of "distress." Therefore, frustration was put in brackets after the word distress in each of the questions. Three items were changed slightly, to add clarity (changes italicized):

- Item 4 (old item 10): “Over the past 4 weeks, when you had sexual intercourse, how satisfied were you with your sense of control over *when you ejaculated?*”.
- Item 5 (old item 11): “Over the past 4 weeks, when you had sexual intercourse, how satisfied were you with the *length of intercourse before ejaculation?*”.
- Item 10 (old item 17): “Over the past 4 weeks, how distressed (frustrated) have you been *about your control over the timing of your ejaculation?*”.

There was some confusion as to the distinction between items 6 and 7; the recommendation was to change the order of these items, to ask more generally about “overall sex life” and then move into specific question about “sexual relationship with partner.”

A further 10 interviews were conducted, incorporating all the changes recommended from the initial interviews. No further changes were recommended based on these additional interviews.

The version shown in Appendix B was the one taken forward for final psychometric testing.

Stage 4: Further Psychometric Analyses

Method

Study Designs

Four studies provided the data for the psychometric analyses:

Studies 1 and 2. Two, fixed-dose, double-blind randomized controlled trials of a new compound for the treatment of PE were conducted in the United States, European Union, Canada, and Australia, and used to carry out the majority of the required psychometric analyses.

Study 3. A separate cohort of men in the United States was recruited to enable test–retest reliability assessment.

Study 4. The fourth study was a general population survey of men in six countries: United Kingdom, the Netherlands, Turkey, Spain, Australia, and United States. These data were used in the assessment of known-groups validity.

Study Populations

Studies 1 and 2. A cohort of 939 men was recruited in studies 1 and 2. These men had to have PE for at least 6 months, fulfill DSM-IV screening criteria, had to be in a heterosexual relationship of greater than 6 months, agree to have inter-

course at least 4 times a month, and have an IELT ≤ 2 minutes in 70% of attempts. Men were also screened to ensure normal erectile function using the Erectile Function Domain of the International Index of Erectile Function [19]. IELT was confirmed via a 4-week period, in which the subject or his partner used a timer to time intravaginal ejaculation latency.

Summary demographics for subjects recruited into studies 1 and 2 were very similar. Age range was 18–65 years, with over 60% in the 18–44 age category for both studies. Overall, most men were Caucasian (86.6%). Mean IELTs for the two groups were very similar (study 1: 54.2 seconds [SD 40.5] vs. study 2: 53.6 seconds [SD 34.2]). Median IELT was 47.8 seconds and 50.5 seconds, respectively. The pooled mean was 53.9 (SD 37.4) seconds and median was 48.8 seconds.

Study 3. A total of 67 men meeting screening criteria for PE (similar to those used in studies 1 and 2, except frequency was $>50\%$) and in a stable, heterosexual relationship of at least 6 months were recruited. Of these, 45 were evaluable, that is, had both initial test and then retest IPE assessments, and had reported no change in their symptoms between the test–retest period. The average period between test and retest was 16.67 (SD 4.32) days.

The men in this study were aged 20–60 years, with a mean age of 36.8 (SD 10.4) years. Seventy-five percent were in the 20–44 age category. Nearly half the men were Caucasian (47.8%), 37.3% were Black/African American, and the rest were Asian or Hispanic. Mean IELT was not collected, but all men reported ejaculating in ≤ 2 minutes at least 50% of the time.

Study 4. Men recruited into the general population survey had to be in a heterosexual relationship of greater than 6 months, and have intercourse at least 4 times a month. Men would *not* be excluded based on the grounds of ejaculatory status or comorbidity. Men were asked if they thought the time they took to ejaculation was “a little quicker than average, about average, a little longer than average.” Using men who reported time to ejaculation as being “about average or a little longer than average” provided a cohort of 418 men classified as “no PE.” Mean age was 38.2 (SD 11.1) years, with 74% of men falling in the 18–44 age category. Most (94.7%) men were of white ethnicity. Mean IELT was 8.9 (SD 7.7) minutes; as expected, this was much higher than in the PE cohort (study 1 and study 2).

Study Procedures

Studies 1 and 2. The men were identified for screening and possible entry into the clinical trials through clinics in the United States, European Union, Australia, and Canada. All men were asked to complete the IPE at the following clinic visits: screening, baseline, 4 weeks, 8 weeks, and 12 weeks. The IPE was administered electronically.

Study 3. Advertisement and telephone screening identified the men. All men attended a site visit, either in Chicago or in New York, to complete the IPE and other questionnaires (completed on paper). A second copy of the IPE was mailed to the men, and they were asked to return it within 2 weeks.

Study 4. The “no PE” group was recruited as part of a large general population survey to assess IELT across different countries: United Kingdom, the Netherlands, Turkey, Australia, and United States. Men were either identified from in-country agency databases or, to a lesser extent, through newspaper advertising. Those recruited were asked to take home a timer (the same used in studies 1 and 2) and record at least 4 IELT attempts.

Statistical Analyses

The same psychometric analyses used for the 17-item version, as detailed in section 3, were repeated for the new 10-item version, to confirm the factor structure and psychometric properties.

Results

Factor Analysis

The same analyses as discussed previously were conducted, to assess if the same domains were present in the modified version of the IPE. A principal components analysis, with promax rotation, was conducted on the 10 items of the IPE. Promax was used rather than varimax because we knew that the domains were correlated based on the previous factor analysis results. Factors 1, 2, and 3 were retained, using the “Eigen values >1.0” rule, which explained 64.29% of the variance.

Factor 1 relates to questions 3,6,7, and 8 of the IPE—sexual satisfaction (factor loadings 0.64–0.86). Factor 2 relates to questions 1, 2, 4, and 5—control (factor loadings 0.57–0.80), and factor 3 relates to questions 9 and 10—distress (factor loadings 0.93 for both items).

This factor solution replicates the version prior to the modifications. Hence, the modifications have not altered the three-factor solution of sexual satisfaction, control, and distress.

Table 2 summarizes the various validity and reliability results and shows that both validity and reliability were confirmed. In addition, convergent validity was tested against IELT and showed all domains were related to this measure.

Discussion

The multifactorial nature of PE suggests strongly that outcome measurement in PE should be more than IELT alone and, through a scientific process, we offer a fully validated, multidimensional, measure to assess domains that are consistent with those proposed by others [11,12] and that more fully characterize this sexual dysfunction: control, sexual satisfaction, and distress.

The development of this instrument involved extensive work, the qualitative research clearly shows the relevance of each of the 10 items, and the psychometric properties of the IPE show it to be very robust. The questionnaire accurately assesses the subjective aspects of PE which patients have identified as being important and relevant to them. Thus, offering a tool for extending the focus of clinical trials in PE beyond IELT and enabling the evaluation of efficacy in domains identified by all classifications [9,13,20,21] as being key to diagnosis and therefore to effective treatment.

By measuring core features of the overall experience of PE, we hope to enable fuller evaluation of available treatments by incorporating important elements of the patient perspective (and possibly also reflecting aspects of partner dissatisfaction). That the tool utilizes patient-evaluated items and has been tested so thoroughly for completeness and comprehension are strengths in an area of sexual dysfunction where the multifactorial nature of PE is difficult to fully capture in single-item patient-reported outcomes.

Future research requires an assessment of the tool’s sensitivity to change and from this work a criterion for what constitutes a meaningful change should start to become apparent. Both anchor-based and distribution-based approaches are recommended as approaches to ascertaining the definition of a minimum important change [22,23].

Note: The IPE is a public-domain instrument available for use by other researchers and has been

Table 2 Further psychometric analyses

Domain	Reliability		Convergent validity		Known groups validity		Normal men		Wilcoxon statistic	P Value	
	Internal consistency	Test-retest reliability	Correlations		PE men		Sample size	Mean (SD)			
			SQL-M	IELT	Sample size	Median					
Sexual satisfaction	0.79	0.83	0.59	0.60	934	10.18 (3.77)	10	17.76 (2.84)	19	25.44	<0.0001
Control	0.70	0.73	0.27	0.75	930	5.65 (2.23)	5	16.81 (3.16)	17	28.64	<0.0001
Distress	0.86	0.72	0.48	0.68	934	4.03 (1.74)	4	9.05 (1.63)	10	27.35	<0.0001

SQL = sexual quality of life; IELT = intravaginal ejaculatory latency time; PE = premature ejaculation; SD = standard deviation.

translated into the following languages: Czech, Dutch, Finnish, French, German, Hebrew, Hungarian, Italian, Norwegian, Polish, Portuguese, Spanish, and U.S. Spanish.

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Conflict of Interest: Drs. Rosen and Althof are consultants for Pfizer, Ltd. Drs. Symonds, Mundayat and May are employees of Pfizer, Ltd.

References

- 1 Spector IP, Carey MP. Incidence and prevalence of sexual dysfunctions: A critical review of the empirical literature. *Arch Sex Behav* 1990;19:389–408.
- 2 Laumann EO, Paik A, Rosen RC. Sexual dysfunctions in the US: Prevalence and predictors. *JAMA* 1999;281:537–44.
- 3 Laumann EO, Nicolosi A, Glasser DB, Paik A, Ginnell C, Moreira E, Wang T. Sexual problems among women and men aged 40–80 years: Prevalence and correlates identified in the Global Study of Sexual Attitudes and Behaviors. *Int J Impot Res* 2005;17:39–57.
- 4 Dunn KM, Croft PR, Hackett GI. Association of sexual problems with social, psychological and physical problems in men and women: A cross-sectional population survey. *J Epidemiol Community Health* 1999;53:144–8.
- 5 Symonds T, Roblin D, Hart K, Althof S. How does premature ejaculation impact a man's life? *J Sex Marit Ther* 2003;29:361–70.
- 6 Rust J, Golombok S, Collier J. Marital problems and sexual dysfunctions: How are they related? *Br J Psychiatry* 1988;152:629–31.
- 7 Sotomayer M. The burden of premature ejaculation: The patient's perspective. *J Sex Med* 2005;2(2 suppl):110–4.
- 8 Pfizer Ltd. PE partner interview study. Data on file 2005.
- 9 Diagnostic and statistical manual of mental disorders, 4th ed. text revision. Washington, DC: American Psychiatric Association; 2000.
- 10 Waldinger MD, Hengeveld MW, Zwinderman AH, Olivier B. An empirical operational study of DSM-IV diagnostic criteria for PE. *Int J Psychiatry Clin Prac* 1998;2:287–93.
- 11 Rowland DL. Treatment of premature ejaculation: Selecting outcomes to determine efficacy. *Bull Int Soc Sex Impot Res* 2003;10:26–27.
- 12 Byers ES, Grenier G. Premature or rapid ejaculation: Heterosexual couples' perceptions of men's ejaculatory behavior. *Arch Sex Behav* 2003;32:261–70.

- 13 American Urological Association. Premature ejaculation: Guideline on the pharmacologic management of premature ejaculation. Xxxx, XX: AUA, Education and Research Inc; 2004.
- 14 Hartmann U. The "PEQUEST": A multidimensional instrument for the assessment of premature ejaculation. San Francisco, CA: International Society for Impotence Research; 1996.
- 15 Yuan YM, Xin ZC, Jiang H, Guo YJ, Liu WJ, Tian L, Zhu JC. Sexual function of premature ejaculation patients assayed with the Chinese Index of Premature Ejaculation. *Asian J Androl* 2004;6:121–6.
- 16 McDowell G, Newell C. Measuring health: A guide to rating scales and questionnaires, 2nd edition. Oxford: Oxford University Press; 1996.
- 17 Symonds T. Sexual quality of life questionnaire for use in men with erectile dysfunction and premature ejaculation. *Int J Impot Res* 2002;14(4 suppl):S87.
- 18 Fayers PM, Machin D. Quality of life: Assessment, analysis and interpretation. Chichester: Wiley; 2000.
- 19 Rosen RC, Riley A, Wagner G, Osterloh IH, Kirkpatrick J, Mishra A. The international index of erectile function: A multidimensional scale for the assessment of erectile dysfunction. *J Urol* 1997;49: 822–30.
- 20 International classification of diseases, 10th revision. World Health Organization; 1989.
- 21 Lue TF, Basson R, Rosen R, Giuliano F, Khoury S, Montorsi F, eds. Second international consultation on sexual medicine: Sexual dysfunctions in men and women. Paris: Health Publications; 2004.
- 22 Guyatt GH, Osoba D, Wu AW, Wyrich KW, Norman GR, Clinical Significance Consensus Meeting Group. Methods to explain the clinical significance of health status measures. *Mayo Clin Proc* 2002;77: 371–83.
- 23 Sloan J, Symonds T, Varga-Chanes D, Fridley B. Practical guidelines for assessing the clinical significance of health-related quality of life changes within clinical trials. *Drug Info J* 2003; 37:23–31.

Appendix A—Initial Item Pool

1. Over the past 4 weeks, how many times did you engage in sexual intercourse?
2. Over the past 4 weeks, prior to sexual intercourse, how willing were you to engage in foreplay?
3. Over the past 4 weeks, prior to sexual intercourse, how often did you limit the amount of foreplay you engage in?
4. Over the past 4 weeks, when you had sexual intercourse, how often did you ejaculate before you were ready?
5. Over the past 4 weeks, when you had sexual intercourse, how often did you have control over when you ejaculated?
6. Over the past 4 weeks, when you had sexual intercourse, how confident were you with your control over ejaculation?
7. Over the past 4 weeks, when you had sexual intercourse, how often were you able to maintain an erection to the point of ejaculation?
8. Over the past 4 weeks, when you had sexual intercourse, how satisfied were you with the quality of your orgasm?
9. Over the past 4 weeks, when you had sexual intercourse, how often was it satisfactory for you?
10. Over the past 4 weeks, when you had sexual intercourse, how satisfied were you with the sense of control over your ejaculation?
11. Over the past 4 weeks, when you had sexual intercourse, how satisfied were you with the time taken for you to ejaculate (duration to ejaculation)?
12. Over the past 4 weeks, when you had sexual intercourse, how satisfied do you think your partner was with the control (or timing) of your ejaculation?
13. Over the past 4 weeks, how satisfied have you been with your sexual relationship with your partner?
14. Over the past 4 weeks, how satisfied have you been with your overall sex life?
15. Over the past 4 weeks, how much did you enjoy sexual intercourse?
16. Over the past 4 weeks, how distressed have you been by your time to ejaculation?
17. Over the past 4 weeks, how distressed have you been by your control over ejaculation?

Appendix B

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These questions ask about the effects your sexual problems have had on your sex life over the past four weeks. Please answer the following questions as honestly and clearly as possible. In answering these questions, the following definitions apply:

- **sexual intercourse** is defined as vaginal penetration (you entered your partner).
- **ejaculation**: the ejection of semen from the penis.
- **control**: ejaculating when you are ready.
- **distress**: meaning how frustrated, disappointed or bothered you are by your premature ejaculation.

Mark only ONE box per question

1. *Over the past four weeks*, when you had sexual intercourse, how often did you have **control** over when you ejaculated?

- No sexual intercourse (not applicable)
- Almost always or always
- More than half the time
- About half the time
- Less than half the time
- Almost never or never

2. *Over the past four weeks*, when you had sexual intercourse, how much **confidence** did you have over when you ejaculated?

- No sexual intercourse (not applicable)
- High confidence
- Moderately high confidence
- Neither high nor low confidence
- Moderately low confidence
- Low confidence

3. *Over the past four weeks*, when you had sexual intercourse, how often was it satisfactory for you?

- No sexual intercourse (not applicable)
- Almost always or always
- More than half the time
- About half the time
- Less than half the time
- Almost never or never

4. *Over the past four weeks*, when you had sexual intercourse, how satisfied were you with your **sense of control** over when you ejaculated?

- No sexual intercourse (not applicable)
- Very satisfied
- Somewhat satisfied
- Neither satisfied nor dissatisfied
- Somewhat dissatisfied
- Very dissatisfied

5. *Over the past four weeks*, when you had sexual intercourse, how satisfied were you with the **length of intercourse** before ejaculation?

- No sexual intercourse (not applicable)
- Very satisfied
- Somewhat satisfied
- Neither satisfied nor dissatisfied
- Somewhat dissatisfied
- Very dissatisfied

6. *Over the past four weeks*, how satisfied have you been with **your** sex life overall?

- Very satisfied
- Somewhat satisfied
- Neither satisfied nor dissatisfied
- Somewhat dissatisfied
- Very dissatisfied

7. *Over the past four weeks*, how satisfied have you been with your sexual relationship **with your partner**?

- Very satisfied
- Somewhat satisfied
- Neither satisfied nor dissatisfied
- Somewhat dissatisfied
- Very dissatisfied

8. *Over the past four weeks*, how much pleasure has sexual intercourse given you?

- No sexual intercourse (not applicable)
- High pleasure
- Moderately high pleasure
- Neither high nor low pleasure
- Moderately low pleasure
- Low pleasure

9. *Over the past four weeks*, how distressed (frustrated) were you by how long you lasted before you ejaculated?

- No sexual intercourse (not applicable)
- Extremely distressed
- Very distressed
- Moderately distressed
- Slightly distressed
- Not at all distressed

10. *Over the past four weeks*, how distressed (frustrated) have you been about your control over ejaculation?

- No sexual intercourse (not applicable)
- Extremely distressed
- Very distressed
- Moderately distressed
- Slightly distressed
- Not at all distressed