ELSEVIER

EDITS: DEVELOPMENT OF QUESTIONNAIRES FOR EVALUATING SATISFACTION WITH TREATMENTS FOR ERECTILE DYSFUNCTION

STANLEY E. ALTHOF, ERIC W. CORTY, STEPHEN B. LEVINE, FREDERIC LEVINE, ARTHUR L. BURNETT, KEVIN McVARY, VERA STECHER, AND ALLEN D. SEFTEL

ABSTRACT

Objectives. To develop Patient and Partner versions of a psychometrically sound questionnaire, the EDITS (Erectile Dysfunction Inventory of Treatment Satisfaction), to assess satisfaction with medical treatments for erectile dysfunction.

Methods. Treatment satisfaction differs from treatment efficacy as it focuses on a person's subjective evaluation of treatment received. Twenty-nine items representing the domain of treatment satisfaction for men and 20 representing partner satisfaction were generated. Two independent samples of 28 and 29 couples completed all items at two points in time. Spearman rank-order correlations were derived to assess test-retest reliability and couple coefficients of validity. Internal consistency coefficients were calculated for both Patient and Partner versions and a content validity panel was used to analyze content validity.

Results. Only items that met all the following criteria were selected to comprise the final questionnaires: (a) range of response four or more out of five; (b) test-retest reliability greater than 0.70; (c) ratings by at least 70% of the content validity panel as belonging in *and* being important for the domain; and (d) significant correlation between the subjects' and partners' responses. Eleven patient items met criteria and formed the Patient EDITS; five partner items met criteria and formed the Partner EDITS. Scores on the two inventories were normally distributed with internal consistencies of 0.90 and 0.76, respectively. Test-retest reliability for the Patient EDITS was 0.98; for the Partner EDITS, it was 0.83.

Conclusions. Reliability and validity were well established, enabling the EDITSs to be used to assess satisfaction with treatment modalities for erectile dysfunction and to explore the impact of patient and partner satisfaction on treatment continuation. UROLOGY **53:** 793–799, 1999.

Significant developments in medical therapies for erectile dysfunction during the past 20 years include more reliable and sophisticated prosthetic devices,[1] new generations of vacuum tumescence devices,[2] refinements in self-injection therapies,[3] innovative transurethral delivery systems,[4] improved techniques for vascular surgery,[5,6] preliminary studies of topical agents,[7] and the development of efficacious oral agents.[8,9]

Although effective treatments have been developed, at least 70% of the population with erectile dysfunction fails to seek help and 30% to 60% of those who do discontinue treatment.[10,11] Clearly, treatment efficacy—the ability to generate a me-

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Requests for copies of the EDITS should be directed to S.E. Althof.

From the Department of Urology, Case Western Reserve University School of Medicine and University Hospitals of Cleveland, Cleveland, Ohio; Center for Marital and Sexual Health, Beachwood, Ohio; School of Humanities and Social Sciences, Penn State Erie, Behrend College, Erie, Pennsylvania; Department of Psychiatry, Case Western Reserve University School of Medicine and University Hospitals of Cleveland, Cleveland, Ohio; Division of Urology, Mount Sinai Hospital, Cleveland, Ohio; Department of Urology, Johns Hopkins University School of Medicine, Baltimore, Maryland; Department of Urology, Northwestern University School of Medicine, Chicago, Illinois; and Pfizer Inc., New York, New York

Reprint requests: Stanley E. Althof, M.D., Center for Marital and Sexual Health, Three Commerce Park Square, 23230 Chagrin Boulevard, Suite 350, Beachwood, OH 44102-5402

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chanically adequate erection—is not the sole determinant of seeking or continuing treatment.

Treatment satisfaction seems relevant to understanding and predicting treatment continuation. Satisfaction measures are intentionally subjective, trying to capture an individual's personal evaluation of the treatment received.[12,13,*] This evaluation includes feelings about the effectiveness of treatment, side effects, ease of use, naturalness, and impact on significant others. For example, it is possible that although a treatment may produce an excellent erection, a patient may rate the treatment as unsatisfactory because the erection was artificially induced, painful to create, failed to enhance the patient's sense of sexual confidence or masculinity, or was not acceptable to the partner.

In the mental health literature, treatment satisfaction correlates with, but is not redundant with, treatment outcome. Attkisson and Zwick[14] and Nguyen *et al.*[15] showed that a general measure of treatment satisfaction had only modest (albeit significant) correlations with *self*-ratings of overall symptom improvement and psychotherapy gain. Other studies have found that a general measure of satisfaction relates to continuation in psychotherapy[16] and mental health treatment.[17]

The goal of the present study was to construct two versions of a psychometrically sound measure of satisfaction with treatments for erectile dysfunction—the Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS). One version was intended to assess patients' treatment satisfaction (Patient EDITS) and the other partners' treatment satisfaction (Partner EDITS). Partner satisfaction has been studied less than patient satisfaction, but seems relevant to understanding treatment continuation for sexual dysfunction, given the dyadic nature of the dysfunction.[18] Our objective was to develop measures that could be used to assess satisfaction and to understand why people stop using efficacious treatments.

MATERIAL AND METHODS

Item Pool Construction

Pools of items for the patient and partner versions of a treatment satisfaction questionnaire were constructed based on reviews of four sources of information: (a) diagnostic criteria for erectile dysfunction, (b) published reports in the area of treatment satisfaction for erectile dysfunction,[19] (c) existing treatment satisfaction inventories, and (d) clinical experience treating patients with erectile dysfunction and their partners.

Items were constructed to be unambiguous and answerable on five-point scales. Twenty-nine items were developed for the patient treatment satisfaction questionnaire and 20 for the partner satisfaction questionnaire. The items were then reviewed by two independent experts[†] and amended per their recommendations. Abbreviated versions of the patient and partner pooled items can be found in Tables I and II, respectively.

Content Validity Panel

Content validity refers to whether items constitute a representative sample of the domain under study.[20] To assess whether the questionnaires represented the domain of treatment satisfaction for patients and partners, we initiated a content validity study. Five mental health[‡] and five urologic[§] experts in the treatment of erectile dysfunction evaluated both questionnaires. For each item the 10 experts were asked to render two judgments on Likert scales: (a) the degree to which the item belongs in the domain of treatment satisfaction for the treatment of male erectile dysfunction, and (b) the importance of the item in the domain of treatment satisfaction.

Reliability and Validity

We were interested in assessing test-retest reliability, internal consistency, and construct validity for both the patient and partner questionnaires. Test-retest reliability was assessed by administering questionnaires to patients and partners on two occasions, not separated by more than 30 days. Spearman rank-order correlations were used to compare the responses to items at time 1 and time 2. Cronbach's alpha was used to assess internal consistency on the time 1 questionnaires.

Treatment satisfaction is subjective and thus a difficult construct to validate. We rejected correlating the EDITS with another treatment satisfaction questionnaire[17] to obtain convergent validity because other questionnaires used items not necessarily related to treatment satisfaction for sexual problems (eg, questions about the attractiveness of the facility and the friendliness of the receptionists), while our questionnaire was focused specifically on satisfaction with medical treatments for erectile dysfunction.

Instead, as the validity criterion for the patient version of the EDITS, the partner's understanding of the patient's feelings about treatment was used. Conversely, the man's perspective of his partner's feelings about treatment was the validity criterion for the partner version of the EDITS. Thus, two additional complementary validity instruments were developed for the purpose of validating the patient and partner versions of the EDITS. These validity instruments included clearly written introductions to explain that the person was to respond, not as themselves but—based on their experience with

* *The evaluation of treatment satisfaction differs from the evaluation of quality of life. Quality of life[14] refers to the subjective evaluation of how a condition and its treatment has an impact on a person's goals, values, and expectations.*

† *Raymond Rosen, Ph.D., Robert Wood Johnson School of Medicine, Piscataway, New Jersey; Taylor Segraves, M.D., Ph.D., Case Western Reserve University School of Medicine, Cleveland, Ohio.*

‡ *Richard Carroll, Ph.D., Northwestern University School of Medicine, Chicago, Illinois; Peter Fagan, Ph.D., Johns Hopkins School of Medicine, Baltimore, Maryland; Derek Polonsky, M.D., Boston, Massachusetts; Candace Risen, L.I.S.W., Case Western Reserve University School of Medicine, Cleveland, Ohio; Patricia Schreiner-Engel, Ph.D., Mount Sinai School of Medicine, New York, New York.*

§ *Donald Bodner, M.D., Case Western Reserve University School of Medicine, Cleveland, Ohio; Arnold Melman, M.D., Albert Einstein School of Medicine, Bronx, New York; Michael O'Leary, M.D., Brigham and Women's Hospital, Boston, Massachusetts; Martin Resnick, M.D., Case Western Reserve University School of Medicine, Cleveland, Ohio; Douglas Swartz, M.D., Jacksonville, Florida.*

TABLE I. *Item selection statistics for items for patient treatment satisfaction questionnaire*

Item No.	Abbreviated Item Content	Panel Saying Item Belongs in Domain (%)	Panel Saying Item Is Important in Domain (%)	Item Range (1–5)	Item Test-Retest Reliability	Item Validity
1	Overall satisfaction with Tx	100	90	4	0.95	0.60
2	Degree Tx met expectations	80	90	4	0.87	0.80
3	How close to being ideal Tx	50	50	4	0.89	0.77
4	How likely to continue using	90	90	4	0.93	0.70
5	How likely to recommend to a friend	30	30	4	0.94	0.48
6	How easy to use Tx	100	100	4	0.71	0.61
7	How physically comfortable to use	80	80	4	0.66	0.45
8	How much interfere sexual activity	60	60	3	0.63	0.64
9	How much affect lifestyle	20	20	1	NS	NS
10	How resentful about needing to use	40	30	3	0.47	NS
11	How much effort to use	50	40	3	NS	0.71
12	How satisfied with how quickly works	90	70	4	0.87	0.58
13	How satisfied with how long lasts	100	80	4	0.93	0.57
14	How affected sense of masculinity	20	20	3	0.79	0.53
15	Degree restored to sexually normal	60	50	4	0.70	NS
16	Impact on confidence to have sex	100	100	4	0.94	0.53
17	How much control over erections	60	60	4	0.91	0.62
18	Does partner know using	60	60	0	NC	NA
19	How feel about partner knowing	50	40	1	NS	NS
20	How easy would it be to conceal	50	30	4	0.66	NS
21	How satisfied is partner with Tx	70	80	4	0.81	0.63
22	How partner feel about your continuing	80	80	4	0.83	0.70
23	How natural process of achieving erection	70	70	4	0.80	0.46
24	Naturalness of erection	80	80	4	0.64	0.46
25	Penile skin sensitivity	40	40	4	0.53	NS
26	Erection size	50	50	4	0.66	NS
27	Erection shape	60	50	4	0.74	NS
28	Erection temperature	10	10	3	0.61	NS
29	Erection hardness	90	70	4	0.79	0.55

KEY: No. = number; Tx = treatment; NC = not calculated; NA = not applicable; NS = not significant at $P < 0.05$.

and intimate knowledge of their partner—as they believed their partner really felt.

SUBJECTS

To test the Patient EDITS questionnaire, 28 couples were recruited from two urology practices in Cleveland, Ohio. Inclusion/exclusion criteria were (a) patient diagnosed with erectile dysfunction and currently receiving medical treatment for it; (b) in a stable heterosexual relationship for more than 6 months; (c) between the ages of 21 and 70; (d) having a female partner willing to participate in the study; and (e) able to read and respond to the questionnaire. All couples provided informed consent. The mean age for the men was 62 years, with a range from 42 to 77; their partners had a mean age of 56 years, with a range from 34 to 77. To treat their erection problems, 13 of the men were using self-injection therapy, 6 were using vacuum erection devices, 3 were using vacuum devices in combination with another form of treatment, 5 were using transurethral therapy (MUSE), and 1 was using testosterone replacement therapy.

For the Partner EDITS version, 29 couples were recruited from urology practices in Chicago, Ill and Baltimore, Md. The same inclusion/exclusion criteria delineated above were used. The mean ages for the men and women were 61 and 57 years, respectively. The men were treating their erectile dysfunction with self-injection (n = 17), vacuum erection devices (n = 7), and oral medication (n = 5).

RESULTS

CONTENT VALIDITY PANEL

Responses of the 10 members of the expert validity panel for each of the questions were dichotomized. Items were considered to have been judged as belonging in the domain if the respondent indicated that it moderately, considerably, or absolutely belonged in the domain; items judged as moderately, considerably, or absolutely important were considered important to the domain. The percentage of the panel that rated each item as belonging in the domain and as important in the domain is shown in Table I for the patient questionnaire and in Table II for the partner questionnaire. We considered an item to have acceptable content validity if 70% of the panel rated it as belonging in the domain *and* as being important in the domain.

TABLE II. *Item selection statistics for items for partner treatment satisfaction questionnaire*

Item No.	Abbreviated Item Content	Panel Saying Item Belongs in Domain (%)	Panel Saying Item Is Important in Domain (%)	Item Range (1–5)	Item Test-Retest Reliability	Item Validity
1	Overall satisfaction with Tx	100	100	4	0.77	0.64
2	Degree Tx met expectations	80	80	4	0.81	0.44
3	How close to being ideal Tx	50	50	4	0.77	0.52
4	How likely to recommend to a friend	30	30	4	0.83	0.49
5	How much interfere sexual activity	60	60	4	0.51	NS
6	How confident about partner's ability	80	80	4	0.64	0.49
7	Restored sense of being sexually normal	50	50	4	0.74	0.40
8	Affected sense of being sexually desirable	70	70	3	0.90	0.65
9	How resentful re Tx for partner	11	11	3	0.83	NS
10	Satisfied with how quickly works	78	44	4	0.62	0.67
11	Satisfied with how long lasts	70	70	4	0.75	0.62
12	Like partner to continue using	90	90	4	0.62	0.46
13	How satisfied thinks partner is	78	67	4	0.68	0.66
14	How partner feels re continuing to use	67	67	4	0.76	0.50
15	Naturalness of erection achieving process	60	50	4	0.80	NS
16	Naturalness of erection	56	67	4	0.73	NS
17	Erection size	56	56	4	0.47	0.71
18	Erection shape	33	33	3	0.78	NS
19	Erection temperature	30	30	3	0.81	−0.54
20	Erection hardness	70	70	4	0.68	0.43

Abbreviations as in Table I.

Item Analysis and Selection

Tables I and II depict the statistics calculated for the 29-item patient and 20-item partner questionnaires. For each item range of response (how many of the five possible choices were used), a test-retest reliability coefficient and a validity coefficient based on the correlation of the targets' responses with the partners' responses to the validity instruments were calculated.

Range of response is analogous to a measure of discrimination.[20] If everyone taking the test gives the same answer to an item, then the item does not differentiate between test-takers and provides no useful information. Only items where respondents employed four or more of the possible five choices were deemed to have sufficient range and included in the final versions.

Test-retest reliability coefficients were calculated for each item using Spearman rank-order correlation coefficients. To be considered for inclusion on the final inventory, an item had to have a reliability coefficient greater than 0.70.

The validity coefficient, also a Spearman rank-order correlation coefficient, was calculated by correlating the target persons' responses with their partners' responses to the similar item on the complementary validation instrument. This correlation had to be positive and significant ($P < 0.05$) to be included as an item in the final scale.

From the patient questionnaire item pool, 11 items (1, 2, 4, 6, 12, 13, 16, 21, 22, 23, and 29) proved satisfactory in terms of *all* the following: (a) evaluation by the content validity panel, (b) range of responses used, (c) test-retest reliability coefficient, and (d) validity coefficient. From the partner questionnaire item pool, 5 items (1, 2, 8, 11, and 14) met the same criteria. These 11 and 5 items, for the patients and partners, respectively, were chosen to comprise the final versions of the Patient and Partner EDITSs and are included in Appendix I and II, respectively.

Scale Construction and Reliability

All items on the 11-item Patient EDITS and 5-item Partner EDITS were scored from zero (no satisfaction or dissatisfaction) to four (high satisfaction). The mean satisfaction score for each patient and partner was calculated. To place scores in an easily interpretable metric, each mean score was multiplied by 25 so that EDITS scores could range from a low of 0 (extremely low treatment satisfaction) to a high of 100 (extremely high treatment satisfaction). In our sample, scores on the patient version ranged from a low of 6.82 to a high of 97.73, with a mean of 66.43; on the partner version, the range of scores was from 10.00 to 100.00, with a mean of 67.87. Scores on both scales were normally distributed, with skewness and kurtosis being within normal limits (−0.81 and −0.10, respectively, for the patient version; −0.79 and −0.28, respectively, for the partner version). Internal consistency (alpha) for the patient version was

0.90 and for the partner version 0.76. Test-retest reliability for the summary score was 0.98 for the patient version and 0.83 for the partner version.

COMMENT

The Patient EDITS and the Partner EDITS are brief, psychometrically sound questionnaires suitable for use in the evaluation of satisfaction with medical treatment modalities for erectile dysfunction. The two inventories have six features that merit their use.

1. The inventories are focused specifically on satisfaction with treatment for erectile dysfunction. They are not measures of treatment satisfaction in general and thus do not ask about things like the attractiveness of the facility or the friendliness of the receptionists. These may be important aspects in treatment satisfaction, but they are not our focus.

2. The inventories assess patient *and* partner satisfaction. Partner satisfaction has seldom been evaluated, although it is probably an important determinant—especially for sexual dysfunction in the context of a dyadic relationship—of continued treatment use. Thus, the EDITSs allow this important area to be measured and investigated.

3. The items in each inventory were selected on the basis of a content validity study. This ensures that the inventories represent relevant domains of treatment satisfaction for patients and for partners.

4. Even in our small samples, almost the entire range of scores (from 0 to 100) for each inventory was used, with the mean being slightly above the midpoint for each scale. Thus, there appears to be neither a floor nor a ceiling effect, allowing these inventories to be used to track change over time.

5. Internal consistency was excellent for the patient version and very good for the partner version. (The shorter length of the partner version explains its lower level of internal consistency.) These high levels of internal consistency suggest that each inventory is unidimensional and measures only one thing—treatment satisfaction.

6. Test-retest reliability was excellent for both inventories. This is not surprising as items were selected for inclusion in part on the basis of a high test-retest reliability coefficient. However, the high test-retest reliability of the inventories suggests that what is being measured—treatment satisfaction—is being measured consistently and that it is not being influenced by error due to fluctuations in such things as a respondent's mood, level of fatigue, or recent sexual experience.

Although the Patient and Partner EDITSs are promising and will, we hope, become the standards in assessing satisfaction with medical treatment for erectile dysfunction, one area that needs further investigation is the construct validity of these inventories. Content validity was assessed, as was construct validity, for individual items. The question in construct validity is whether a measure behaves as theory predicts the construct should behave. Thus, for example, one might predict that people who receive an active treatment should be more satisfied than those who receive a placebo treatment or that one form of treatment, because it is easier to administer or has fewer side effects, should lead to more satisfaction than another form of treatment. At present the EDITS is being used in the United States and abroad to examine the degree of satisfaction with different treatment modalities. Data from studies such as these will be used to evaluate the construct validity of the Patient and Partner EDITS.

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APPENDIX I. THE EDITS: ERECTILE DYSFUNCTION INVENTORY OF TREATMENT SATISFACTION, PATIENT VERSION

Stanley E. Althof, Ph.D. & Eric W. Corty, Ph.D.

Name or ID number: _____

Date: _____

What treatment method are you currently using? _____

The questions in this inventory ask about a sensitive topic, your sexual life with your wife or partner as well as your attitude toward and expectations from the treatment method you are using to help with your erection problem. Please answer the questions as honestly and candidly as you can. If any questions or terms are unclear, please ask for clarification.

1. Overall, how satisfied are you with this treatment?
   a. Very satisfied
   b. Somewhat satisfied
   c. Neither satisfied nor dissatisfied
   d. Somewhat dissatisfied
   e. Very dissatisfied
2. During the past four weeks, to what degree has the treatment met your expectations?
   a. Completely
   b. Considerably
   c. Half way
   d. A little
   e. Not at all
3. How likely are you to continue using this treatment?
   a. Very likely
   b. Moderately likely
   c. Neither likely nor unlikely
   d. Moderately unlikely
   e. Very unlikely
4. During the past four weeks, how easy was it for you to use this treatment?
   a. Very easy
   b. Moderately easy
   c. Neither easy nor difficult
   d. Moderately difficult
   e. Very difficult
5. During the past four weeks, how satisfied have you been with how quickly the treatment works?
   a. Very satisfied
   b. Somewhat satisfied
   c. Neither satisfied nor dissatisfied
   d. Somewhat dissatisfied
   e. Very dissatisfied
6. During the past four weeks, how satisfied have you been with how long the treatment lasts?
   a. Very satisfied
   b. Somewhat satisfied
   c. Neither satisfied nor dissatisfied
   d. Somewhat dissatisfied
   e. Very dissatisfied
7. How confident has this treatment made you feel about your ability to engage in sexual activity?
   a. Very confident
   b. Somewhat confident
   c. It has had no impact
   d. Somewhat less confident
   e. Very much less confident
8. Overall, how satisfied do you believe your partner is with the effects of this treatment?
   a. Very satisfied
   b. Somewhat satisfied
   c. Neither satisfied nor dissatisfied
   d. Somewhat dissatisfied
   e. Very dissatisfied
9. How does your partner feel about your continuing to use this treatment?
   a. My partner absolutely wants me to continue
   b. My partner generally prefers me to continue
   c. My partner has no opinion
   d. My partner generally prefers me to stop
   e. My partner absolutely wants me to stop
10. How natural did the process of achieving an erection feel when you used this treatment over the past four weeks?
    a. Very natural
    b. Somewhat natural
    c. Neither natural nor unnatural
    d. Somewhat unnatural
    e. Very unnatural
11. Compared to *before you had an erection problem* how would you rate the naturalness of your erection when you used this treatment over the past four weeks in terms of hardness?
    a. A lot harder than before I had an erection problem
    b. Somewhat harder than before I had an erection problem
    c. The same hardness as before I had an erection problem
    d. Somewhat less hard than before I had an erection problem
    e. A lot less hard than before I had an erection problem

Thank you for having completed the questionnaire.

APPENDIX II. THE EDITS: ERECTILE DYSFUNCTION INVENTORY OF TREATMENT SATISFACTION, PARTNER VERSION

Stanley E. Althof, Ph.D. & Eric W. Corty, Ph.D.

Name or ID number: _____

Date: _____

What treatment method is your husband or partner currently using for his erection problem? _____

The questions in this inventory ask about a sensitive topic, your sexual life with your husband or partner as well as your attitudes and experiences regarding treatment for his erection problem. Please answer the questions as honestly and candidly as you can. If any questions or terms are unclear, please ask for clarification.

1. Overall, how satisfied are you with this treatment for your husband's or partner's erection problem?
   a. Very satisfied
   b. Somewhat satisfied
   c. Neutral; neither satisfied nor dissatisfied
   d. Somewhat dissatisfied
   e. Very dissatisfied
2. During the past four weeks, to what degree has the treatment met your expectations?
   a. Completely
   b. Considerably
   c. Half way
   d. Somewhat
   e. Not at all
3. Over the past four weeks, how has this treatment affected your sense of being sexually desirable?
   a. It has made me feel much more sexually desirable
   b. It has made me feel somewhat more sexually desirable
   c. It has had no impact on my sense of being sexually desirable
   d. It has made me feel somewhat less sexually desirable
   e. It has made me feel less sexually desirable
4. Over the past four weeks, how satisfied have you been with how long this treatment enhances your husband's or partner's ability to achieve an erection?
   a. Very satisfied
   b. Somewhat satisfied
   c. Neutral, neither satisfied nor dissatisfied
   d. Somewhat dissatisfied
   e. Very dissatisfied
5. How do you think your husband or partner feels about continuing this treatment?
   a. I think that he very much wants to continue using this treatment
   b. I think that he somewhat wants to continue using this treatment
   c. I think my partner feels neutral about continuing to use this treatment
   d. I think that he somewhat wants to discontinue using this treatment
   e. I think that he very much wants to discontinue using this treatment

Thank you for having completed the questionnaire.