

The Erectile Function Visual Analog Scale (EF-VAS): a disease-specific utility instrument for the assessment of erectile function

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This article presents the responsiveness results of the Erectile Function Visual Analog Scale (EF-VAS) and reports, for the first time, utilities associated with erectile dysfunction (ED), as calculated by a disease-specific utility assessment. The EF-VAS is a new quality of life (QoL) instrument specific to ED that combines the strengths of the disease-specific approach to measuring QoL (greater disease relevance and responsiveness, with relevance to clinicians and patients) with those of preference-based assessments (generalizability and relevance to decision makers). The EF-VAS has demonstrated feasibility, reliability, and validity as reported in a recent publication.¹

Methods: Standard instrument development methodology was utilized and the finalized content was integrated into a preference based scoring instrument comprised of two visual analogue scales (VAS). The EF-VAS was implemented in a clinical trial and data from the trial was subjected to

validation analysis. Three methods were used to evaluate the responsiveness of the EF-VAS: Spearman correlations, effect size and standardized response means. VAS scores were converted to von Neumann-Morgenstern (vNM) utilities through a conversion curve.

Results: The EF-VAS was established to be responsive to changes in disease state within and between patients with ED. The EF-VAS allowed the calculation of vNM utility values and a significant increase in utility was observed in the sildenafil group compared to placebo at study end.

Conclusion: The EF-VAS represents an important advance in the understanding of the impact of ED on patients' QoL and in providing a mechanism to allow the quantification of the health status that patients associate with ED. Based on its responsiveness, the EF-VAS will provide an important clinical tool to assess and contribute to the understanding of the impact of treatment for ED. The EF-VAS represents a major advance in the science of health-related quality of life (HRQoL) assessment, as it is the first validated ED-specific utility assessment reported in the literature.

Key Words: erectile dysfunction, quality of life instrument, utility

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Introduction

ED is defined as the inability to achieve and/or maintain an erection adequate to undertake satisfactory intercourse.² According to the NIH Consensus panel, ED affects up to 30 million men in the United States.² It is well accepted that reduced frequency of sexual intercourse is accompanied by feelings of low self-esteem, poor self-image, mental stress and depression,³ all of which negatively impact the QoL of sufferers.^{3,4} Management of ED should therefore address psychological aspects of ED, and this requires inclusion of QoL measures when assessing response to treatment for ED.

Traditionally, QoL instruments are classified as either disease specific or generic. The disease specific

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measures are generally more sensitive to subtle changes in the disease, and therefore are more relevant to patients and clinicians. However, they lack generalizability beyond the specific disease. Generic measures, on the other hand, provide broad generalizability, and thus are more relevant to decision makers with broad responsibility for program support and budget decisions. Utility measures, one of the generic approaches, enable the calculation of quality adjusted life years (QALYs) and therefore provide the data for cost effectiveness and particularly cost utility analyses.^{5,6} While there are several disease specific instruments that have recently been developed and validated to assess QoL in ED, none of them include preference measurements or utilities, which would allow the calculation of cost effectiveness or cost utility in ED.

EF-VAS is a new validated QoL instrument that combines the strengths of the two approaches to QoL assessment: the sensitivity and relevance of a disease specific instrument and the generalizability and the decision support power of a generic preference-based instrument. As such, the EF-VAS represents an important advance in the science of QoL assessment. The EF-VAS demonstrated feasibility, reliability, and validity as reported in a recent publication.¹ Herein, we present the responsiveness results of the EF-VAS, as well as the vNM utilities associated with ED, as measured by the EF-VAS. Utilities represent preference-based measures of QoL and are generally expressed by a value ranging from 0 (death) to 1 (perfect health).

While it is important to measure change in disease state in response to treatment, it is equally important to be able to quantify patient preferences for outcomes, such as changes in QoL that may result from pharmacological treatment. A facet of ED research and management that has been missing to date is the ability to place patient preferences for ED within a framework that incorporates other disease states with known impact on QoL and established utility values. Such information is required as an important element in developing informed policy and clinical decisions about ED treatment.

Importantly, and differing from most applications of conventional utility measurements such as time trade off (TTO) and standard gamble (SG) assessments, it is not necessary to have the EF-VAS administered by trained interviewers as this scale is designed to be self administered. The EF-VAS was developed and validated as a preference-based assessment in ED that is appropriate for use by clinicians, researchers and health economists, and

which can be administered as a self completed instrument with a minimum degree of burden to patients.

Of importance, the EF-VAS is the first validated ED-specific QoL instrument that allows the calculation of utilities (i.e., patient preferences).

Methods

The EF-VAS was developed utilizing standard instrument development methodology.¹ The VAS methodology for preference measurement was utilized in this instrument because it is simple and can be self-administered. The VAS is relatively simple to implement as compared to alternative instruments such as the SG and TTO techniques. In the VAS methodology, patients are asked to score health states on a VAS marked from 0 to 100, with 100 representing perfect health and 0, death. Differences between health states on the scale correspond to the differences in the strength of preferences for the health states. In addition, VAS scores can be converted to vNM utilities (i.e. QoL) through an appropriate conversion curve.⁷

The classification system associated with this instrument consisted of eight domains related to ED and then five levels within each domain. The preference measurement system consisted of two VAS scales. The first (VAS-1) is an ED disease-specific scale in which preferences are measured among disease states for the disease in question. Scale 2 (VAS-2) is a generic scale, which prompts the respondent to place ED within the larger context of a traditional utility scale ranging from 0 (dead) to 1 (perfect health). The EF-VAS was developed in English and French Canadian. Therefore, the validation analyses apply to the psychometric properties of the EF-VAS in both languages. A copy of the EF-VAS (English) is provided at the end of the manuscript.

The administration of the EF-VAS consists of four steps: Step 1) the patient answers eight questions describing his ED experience over the past 4 weeks; Step 2) the patient ranks four health states from most desirable to least desirable. Three states are clinical states (i.e., mild, moderate, and severe ED) and the fourth state corresponds to the subject's self-state (denoted as S hereafter); Step 3) the patient completes the VAS1 scale, which is ED specific and Step 4) the patient completes the VAS2, the generic scale. In the VAS1 scale, (Step 3), patients assess their own state (i.e. how patients perceive their own ED health state) in relation to the three clinical marker states (mild, moderate, and severe ED) and in relation to the upper anchor of the scale (perfect health). To compute the

preference scores on a conventional dead-healthy 0-1 scale, the self state scores from the VAS1 scale (S-VAS1) are converted to their equivalent self-state scores on VAS2 (S-VAS2) using the two states that are measured in both the scales (perfect health and the least desirable state from VAS1).

Validation analyses (feasibility, reliability, validity and responsiveness) were conducted using responses from 169 ED patients enrolled in a 12-week, Canadian, double-blind, randomized, placebo-controlled, parallel group, multicentre, flexible dose study of sildenafil citrate in male patients with ED. Inclusion criteria for participation in the clinical study required that patients had been diagnosed with ED and were in a stable relationship. The EF-VAS was administered at week -1 (screening), at week 0 (baseline), and at week 12 (end of study). At screening 169 individuals with ED completed the EF-VAS, with 164 at baseline and at the end of the study. Missing responses were evaluated as part of the feasibility assessment, and as such are included in the analysis. These data were used to establish the measurement properties of the instrument in terms of feasibility, reliability, validity, and responsiveness, as well as to calculate utility values for ED in this group. The development and complete description of the EF-VAS, the baseline characteristics of the population enrolled in this study and the methodology used to evaluate the feasibility, reliability, and validity of the EF-VAS have been recently reported.¹

The responsiveness of an instrument determines whether the instrument can measure changes in the disease state over time within patients. As the disease state improves the score of the VAS should increase and as the disease state worsens the score of the VAS should decrease. Three methods were used to evaluate the responsiveness of the EF-VAS: Spearman correlations, effect size (ES) and standardized response means (SRM).

In a first step, correlations between the change in clinical measures of ED and the change in the scores of the VAS were conducted at baseline and end of study for the treatment and placebo groups combined. The direction of the change should be the same and the size of the change should be monotonically related (i.e., larger change in one should correspond with larger change in the other). The agreement in the direction of change (i.e., improved; no change or worsened) for the scores of the VAS and the disease severity were compared using Spearman's Correlation. Disease severity was assessed using the criteria for severity established in the Erectile Function (EF) domain of the International Index of Erectile

Function (IIEF),⁸ the IIEF questions 3 and 4⁹ and the Sexual Health Inventory for Men (SHIM).^{10,11}

To measure the magnitude of change over time, the ES for the scores of the VAS in each treatment group was determined and compared.¹² The ES is defined as the difference between two means divided by a standard deviation, and provides an estimate of the magnitude of between group differences. In this case, the denominator is the standard deviation of the EF-VAS at baseline. The ES was calculated for scores of the two scales of the EF-VAS (i.e., VAS1 and VAS2), the EF domain of the IIEF, the IIEF Q3 and Q4 and the SHIM, by dividing the mean change score (termination score minus baseline score) by the standard deviation of scores at baseline. An ES between 0.2 to <0.49 indicates a small to moderate effect, 0.5 to 0.79 indicates a moderate to large effect, and 0.8 or greater indicates a large effect. In the last step of the responsiveness analysis, the SRMs for the S-VAS1 and S-VAS2, the IIEF EF Domain, the IIEF Q3 and Q4 and the SHIM, were calculated to measure the sensitivity of the instrument, by dividing the mean change score (termination score minus baseline score) by the standard deviation of the change scores.¹³

The VAS approach is well established as obtaining valid information on ordinal preferences (rankings), but this approach does not directly provide cardinal preferences (utilities). In fact, Torrance first reported in 1976 that the VAS results do not agree perfectly with the SG results, the VAS scores being consistently lower than those generated via SG techniques.¹⁴ However VAS scores can be converted to vNM utilities through an appropriate conversion curve, which has been shown to be concave.⁷

Results

The results reported in this paper focus on the results of the responsiveness analyses for the EF-VAS. The validation analyses of feasibility, validity and reliability have been previously reported.¹ To summarize these results, the feasibility of the instrument was found to be good. In the first administration of the EF-VAS 89% of participants rated the questionnaire as easy to complete. This proportion grew to 93% by the second administration. The mean time to complete the instrument was 30 minutes on the first administration and 18 minutes on the second. As well, the instrument was found to have face and construct validity with the VAS scores for the self state found to be positively and statistically significantly correlated with disease severity. In testing for reliability, the variance between patients

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and within patients at screening and week one were tested. The instrument demonstrated appropriate 1 week test retest reliability, with all parameters exceeding the threshold of an Intra-Class Correlation Coefficient (ICC) of 0.7 established *a priori*.

With regard to the responsiveness of the EF- VAS the Spearman correlations for change in disease (IIEF Q3 and Q4) with change in VAS score were positive and statistically significant, as hypothesized, but modest in magnitude with values of 0.346 for S-VAS1 and 0.298 for S-VAS2. The direction of change was found to be moderately correlated for S-VAS scores and the SHIM with Spearman's rank correlation coefficient of 0.451 for S-VAS1 and 0.379 for S-VAS2. When each of the two scales were examined separately the score for S-VAS1 and the SHIM had a Spearman's rank correlation coefficient of 0.45 and 0.38 for the S-VAS2. Similar correlations were found when the analysis measured change in VAS score against the EF domain for the IIEF (correlation of 0.44 and 0.37 respectively).

In evaluating the responsiveness of the EF-VAS by treatment group (placebo versus sildenafil) the change from baseline to week 12 for the sildenafil group was 0.14 for S-VAS1 and 0.08 for S-VAS2, both statistically significantly different from zero. As expected, the change from baseline to study end for the placebo group was not statistically significant as demonstrated by the 95% confidence interval, which includes 0. For both the scales (VAS1 and VAS2) the difference between the two groups (placebo versus sildenafil) was statistically significant, indicating that, in the ED population, the S-VAS1 and S-VAS2 were able to distinguish between active treatment with sildenafil and non-active treatment groups. Table 1 displays the confidence intervals and the t-test results comparing the difference between groups against zero for the S-VAS1 and S-VAS2. These results indicate an

improvement in the self-perception of ED status among sildenafil treated men.

The S-VAS1 and S-VAS2 had SRMs of 0.49 and 0.40 respectively. The SRMs for the IIEF EF domain, IIEF Q3 and Q4 and the SHIM were similar with values of 0.89, 0.97, and 0.87 respectively. These values indicate that the disease-specific questionnaires are able to differentiate between the two treatment groups and measure a separation of approximately 1 standard deviation (SD). The S-VAS1 is not as strong as the other scales in detecting differences between the two groups, but it is still able to do so. Interestingly, and somewhat unexpectedly, the VAS2, which is not disease specific, is able to differentiate between the groups almost as well as the VAS1 (disease specific) scale.

The results of the responsiveness analysis (i.e., t-test, ES, and SRM) consistently demonstrate that the EF-VAS scales are able to detect a change in disease state in response to treatment. The graphic representation of the responsiveness data by treatment group for the VAS1 (i.e., ED specific scale) by change of EF domain clearly illustrates the anticipated groups of scores, appropriately clustered in the anticipated quadrants of the graph, Figure 1. That is, in general, patients whose ED worsened had S-VAS1 scores that decreased, while patients whose ED improved had S-VAS1 scores that increased.

The conversion curve used to transform the raw VAS scores into vNM utilities is represented in Figure 2. The resulting conversion curve was found to be similar to those for other disease states.⁷ The results of the conversion indicated that at the baseline visit, the transformed vNM utilities ranged between 0 and 1.0, with a mean of 0.81 (SD=0.203). At the end of treatment, the vNM utility for the placebo group was 0.820, a value very close to the original baseline score of 0.821. However, significant differences were seen in the sildenafil group where the vNM utility

TABLE 1. Self scores: response (mean change) by treatment group and statistical differences for responsiveness

	Group	N	Mean change	SD	(Lower 95%, Upper 95%)	t Value	Pr > t
Self score-VAS1	Sildenafil Citrate	83	0.1427	0.2812	(0.0813, 0.204)		
	Placebo	81	0.0044	0.2881	(-0.059, 0.0681)		
	Difference		0.1382	0.2846	(0.0504, 0.226)	3.11	0.0022
Self score-VAS2	Sildenafil Citrate	81	0.0972	0.2261	(0.0472, 0.1472)		
	Placebo	78	0.0174	0.1727	(-0.022, 0.0564)		
	Difference		0.0797	0.2017	(0.0165, 0.1429)	2.50	0.0134

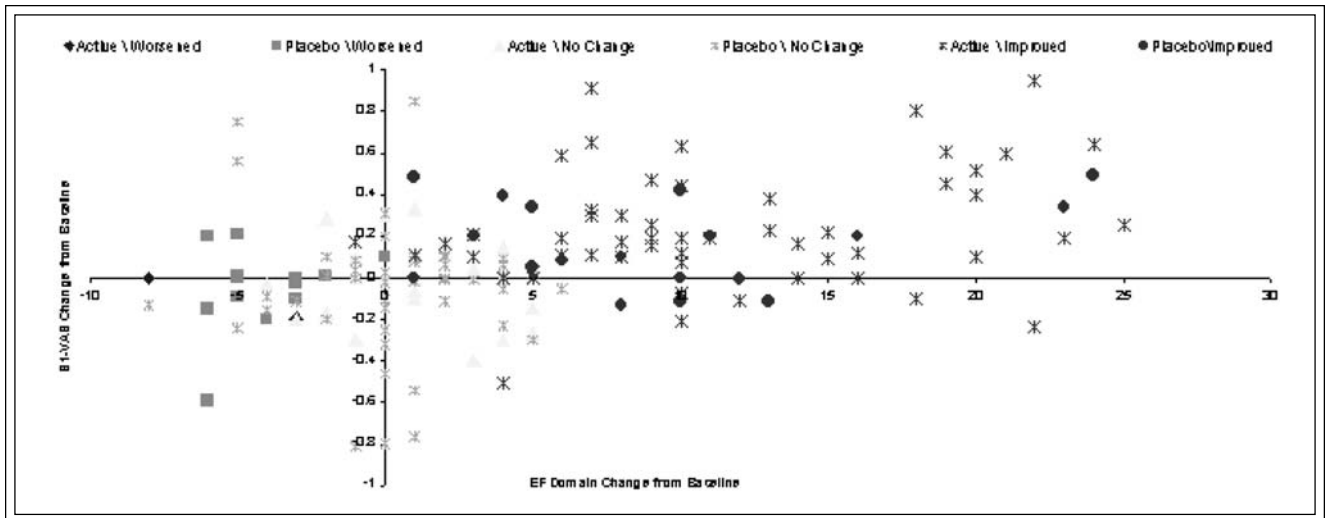


Figure 1. Response by treatment group, comparison of EF domain with VAS1 by change in EF-domain grade.

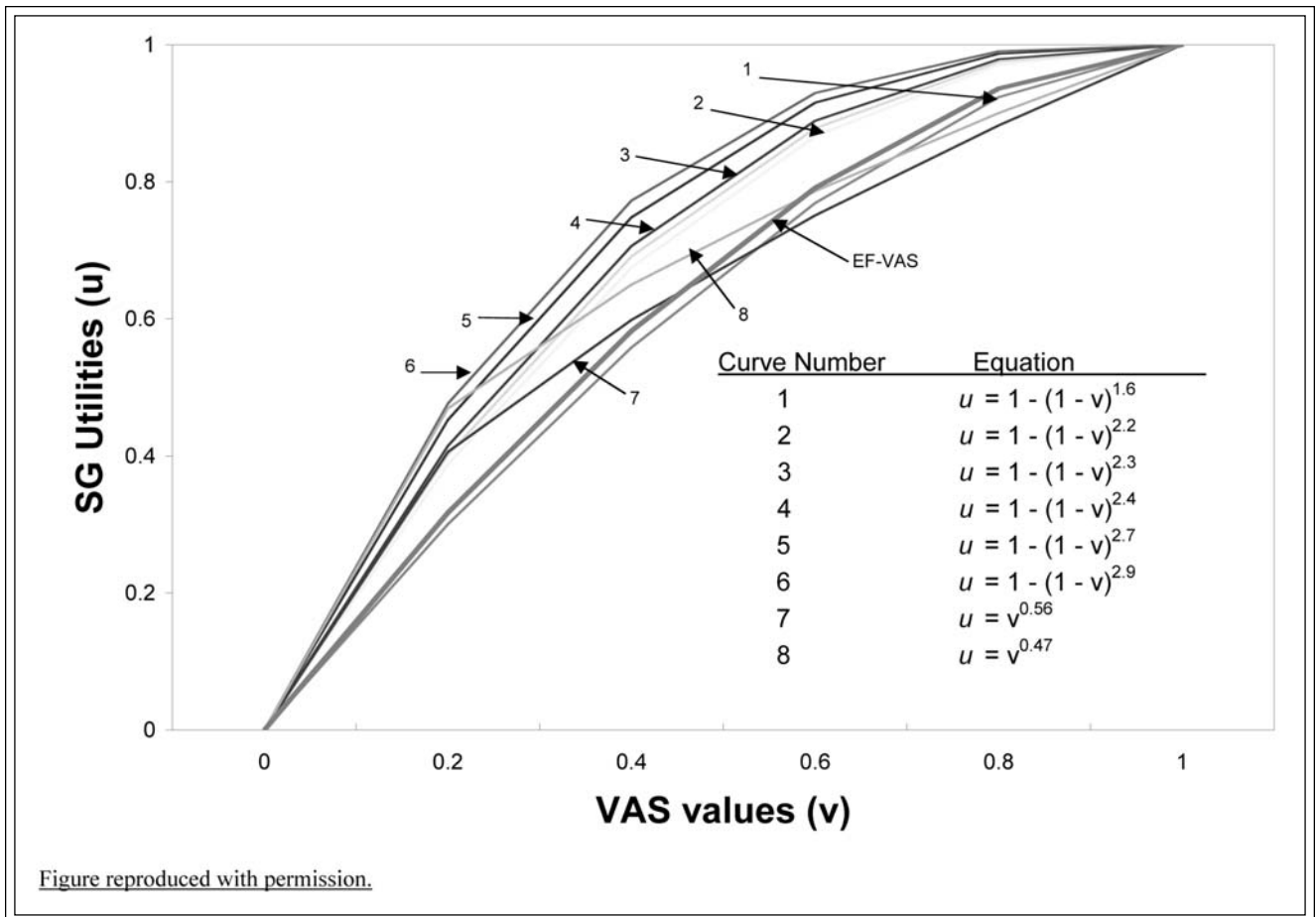


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Figure 2. Conversion curve for EF-VAS in context of other curves. A conversion curve was calculated for the EF-VAS to convert VAS values to vNM utilities.⁷ As demonstrated, the curve for EF-VAS is similar to published curves derived for other disease states. The conversion curve was based on a known health state that was included in the EF-VAS, and which has an established vNM utility score.

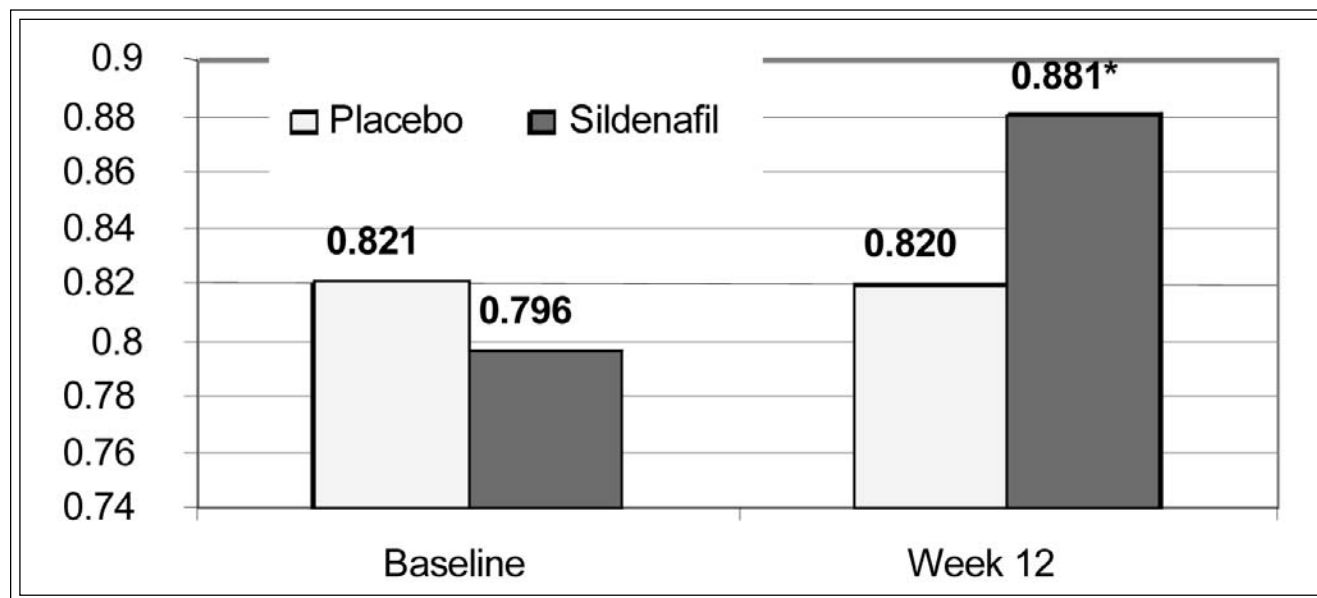


Figure 3. vNM utility scores by treatment group.

after treatment was calculated to be 0.881 ($p=0.007$), a significant difference from the 0.796 established in the sildenafil group at week 0. These vNM utility values are presented in Figure 3.

Discussion

The analyses of this data set indicate that the EF-VAS is responsive to changes in disease state and is able to differentiate between treatment groups. The EF-VAS can be utilized to calculate utility values for individuals with ED and these utility values can be compared with those for other medical conditions, a comparison which had not been possible before.

The gold standards for the collection of utility data to date have included the TTO and SG methodologies, both of which typically require in-depth and lengthy interviews by trained interviewers. The need for interviewers is mandated by the complexity of the concepts and tasks involved in these methods. The approach used with the EF-VAS eliminates this complexity, resulting in a more efficient form of data collection, with a less onerous time burden on respondents. While it was anticipated that patients may have had some difficulty with the concepts underlying the EF-VAS, the vast majority of patients (about 90%) completed the questionnaire with no missing responses and no obvious errors, and more than 90% of the patients indicated that they found the entire EF-VAS to be easy to complete. In addition, the EF-VAS has a distinct advantage in the field of ED

where respondents prefer to participate in self-administered assessments, providing more honest answers in this setting.^{15,16}

The responsiveness of the EF-VAS is positive. One of the methodological challenges of combining a generic preference based approach with a disease specific approach is the ability to retain the strengths of both approaches, including sensitivity to the disease in question. The positive responsiveness of the EF-VAS demonstrates that this instrument meets the requirements of a disease specific instrument (VAS1 scale) in that it is sensitive to the nuances of the disease in question. The VAS2 scale, which is not disease specific, is able to differentiate between the treatment groups almost as well as the VAS1 scale. This was an unexpected, but very positive finding.

It is important, both from a clinical and a policy perspective, to understand how patients perceive the impact of a disorder such as ED in relation to other disorders. Through the use of a conversion curve, the VAS scores can be converted into vNM utilities. The resulting conversion curve was found to be similar to those for other disease states.⁷ The ability to calculate utilities for any disease or disorder allows that health state to be put in the context of other diseases, thus allowing the conduct of meaningful cost-utility analyses for informing health decision makers. This has not previously been possible with any of the existing measures of QoL in ED.

Within the scope of this instrument development and validation analysis it was not possible to encompass the

requirement for a similar measure to examine either female sexual dysfunction or the impact of ED on a partner. The role of the EF-VAS in assessing female sexual dysfunction and/or impact of ED on a partner could be explored in future research.

Results confirm that ED has a profound impact on QoL and are consistent with other research related to utility values in ED. The mean vNM utility value at baseline was comparable with other states that have a known impact on QoL. For example, the utility value for people who have suffered a minor stroke with no major sequelae has been reported to range from 0.81 to 0.87.^{17,18} In interpreting these utilities it is important to remain cognizant of the fact that various methods were utilized to calculate utilities in the studies (i.e. TTO, SG, HALEX, HUI3). The utility score for ED calculated with the EF-VAS is also comparable with utility values for ED, as established by other researchers (0.76 to 0.87).¹⁹⁻²¹ Newly reported research has confirmed this range of utilities for ED, using TTO, SG and VAS scores to calculate utilities for ED in 89 men.²² This study included control subjects without ED, and analyses of these data

demonstrated that utilities for men with ED were significantly lower as measured by VAS and TTO when compared to the control subjects. Previously established utility values for other health states, as compared to the utility calculated with the EF-VAS for ED are summarized in Table 2.

Patient perception of QoL (i.e. utility) is increased after 12-weeks of sildenafil treatment versus placebo. From baseline to study end, a statistically significant increase in the utility (from 0.796 to 0.881) was observed in the sildenafil group. As expected, no change (from 0.821 to 0.820) was observed in the placebo group between baseline and end of study. An understanding of these values allows clinicians and policy makers to place ED within a meaningful context, as it compares to other health states.

This newly developed and methodologically novel disease specific utility instrument allows the impact of ED to be assessed in relation to other health related conditions that are known to impact QoL. The EF-VAS has been able to achieve the benefits of both a generic instrument (generalizability and calculation of patient preferences or utilities) and a disease specific

TABLE 2. Utilities for EF-VAS in context of utilities for other health states

	Utility	Method of assessment
Patients awaiting lung transplant ¹	0.50	SG
Breast cancer, advanced ²	0.62	TTO
Melanoma (immediately after diagnosis) ³	0.73	HALex
Rheumatoid arthritis ⁴	0.77	TTO
Back problems ⁵	0.81 ± 0.19	HUI Mark III
Erectile dysfunction (no treatment)	0.821	EF-VAS
Minor stroke, no sequelae ⁶	0.81 – 0.87	Meta analysis
Osteoarthritis (hip or knee) ⁷	0.84	TTO
Erectile dysfunction (12-week sildenafil treatment)	0.88	EF-VAS
Asthma ⁸	0.91	SG
Visual loss associated with diabetic retinopathy (mild) ⁹	0.91	TTO
Cystic Fibrosis (adolescent) ¹⁰	0.92	SG

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instrument (sensitivity to QoL impact on specific populations or diseases) combined in one feasible assessment. The information garnered from future administrations of the EF-VAS will add important knowledge in this regard.

Treatment satisfaction has been identified as a pivotal characteristic in maintaining long-term therapy for ED^{23,24} and the EF-VAS offers a new mechanism to measure treatment satisfaction in a quantifiable way. It is anticipated that the EF-VAS will demonstrate the extent to which those suffering from ED value normal EF and its associated domains in terms of preferences for described health states. Researchers, decision-makers, and health care professionals will now be able to position ED within the much broader context encompassed within utility assessment. □

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<p>Permission granted from Pfizer Canada Inc. to reproduce the questionnaire</p> <h2 style="text-align: center;">Erectile Function Visual Analog Scale EF-VAS</h2> <p>Patient Instructions</p> <p>Your participation is entirely voluntary and if there are any items that you would rather not respond to, you may skip to the next one. All of the questions you will answer deal with your opinion. Therefore, there are no right or wrong answers, and everyone's opinions differ on these matters. You do not have to explain your answers. All we want is your opinion.</p> <p>Someone who is familiar with the study will give you instructions on how to complete the exercises. The same person will look at the forms after you have completed them to make sure that nothing has been forgotten.</p> <p>This exercise involves:</p> <ol style="list-style-type: none"> 1. A group of questions to assess your experience with erectile dysfunction 2. A visual scale, numbered 0 to 100, which is designed to indicate your feelings about different aspects of your condition. The scale is used to measure your preferences for different health states and how they relate to each other <p>©2005 Pfizer Canada Inc.</p>	<h3 style="text-align: center;">STEP 1 (continuation)</h3> <ol style="list-style-type: none"> 4. Over the past four weeks, how did you react in situations that usually could result in sexual activity? <ul style="list-style-type: none"> <input type="checkbox"/> Did not avoid situations that usually could result in sexual activity <input type="checkbox"/> Occasionally avoided situations that usually could result in sexual activity <input type="checkbox"/> Often avoided situations that usually could result in sexual activity <input type="checkbox"/> Always avoided situations that usually could result in sexual activity 5. Over the past four weeks, how would you describe your mood? <ul style="list-style-type: none"> <input type="checkbox"/> Normal mood <input type="checkbox"/> Occasionally felt low, irritable or tense <input type="checkbox"/> Often felt low, irritable or tense <input type="checkbox"/> Almost always felt low, irritable or tense 6. Over the past four weeks, how much of an impact did your sexual difficulties have on your everyday activities? <ul style="list-style-type: none"> <input type="checkbox"/> Functioned normally at work/home <input type="checkbox"/> Occasionally distracted at work/home thinking about sexual difficulty <input type="checkbox"/> Often distracted at work/home thinking about sexual difficulty <input type="checkbox"/> Continually distracted at work/home thinking about sexual difficulty 7. Over the past four weeks, how satisfied have you been with the sexual aspects of your relationship? <ul style="list-style-type: none"> <input type="checkbox"/> Very satisfied with sexual aspects of relationship <input type="checkbox"/> Moderately satisfied with sexual aspects of relationship <input type="checkbox"/> Moderately dissatisfied with sexual aspects of relationship <input type="checkbox"/> Very dissatisfied with sexual aspects of relationship 8. Over the past four weeks, how satisfied have you been with the non-sexual aspects of your relationship? <ul style="list-style-type: none"> <input type="checkbox"/> Very satisfied with non-sexual aspects of relationship <input type="checkbox"/> Moderately satisfied with non-sexual aspects of relationship <input type="checkbox"/> Moderately dissatisfied with non-sexual aspects of relationship <input type="checkbox"/> Very dissatisfied with non-sexual aspects of relationship <p>©2005 Pfizer Canada Inc.</p>
<h3 style="text-align: center;">STEP 1</h3> <p>For the series of questions below please think about your experience with erectile dysfunction. Remember that there is no "correct" answer to any of these questions. This exercise will help to determine where you see yourself in terms of the impact of erectile dysfunction on your life. Think about your experience over the past four weeks and place a checkmark (✓) in the box that describes your situation most accurately.</p> <ol style="list-style-type: none"> 1. Over the past four weeks, how would you describe the quality of your erections? <ul style="list-style-type: none"> <input type="checkbox"/> Almost always/always attained erections that were firm enough and lasted long enough for sexual activity <input type="checkbox"/> Most times attained erections that were firm enough and lasted long enough for sexual activity <input type="checkbox"/> Occasionally attained erections that were firm enough and lasted long enough for sexual activity <input type="checkbox"/> No erections at all 2. Over the past four weeks, how would you describe your sexual drive and sexual interest? <ul style="list-style-type: none"> <input type="checkbox"/> Usual sexual drive/interest <input type="checkbox"/> A little less sexual drive/interest than usual <input type="checkbox"/> Significantly less sexual drive/interest than usual <input type="checkbox"/> No sexual drive/interest 3. Over the past four weeks, how satisfied have you been with your self-image, as far as your sexuality is concerned? <ul style="list-style-type: none"> <input type="checkbox"/> Very satisfied with self-image (as far as sexuality is concerned) <input type="checkbox"/> Moderately satisfied with self-image (as far as sexuality is concerned) <input type="checkbox"/> Moderately dissatisfied with self-image (as far as sexuality is concerned) <input type="checkbox"/> Very dissatisfied with self-image (as far as sexuality is concerned) <p>©2005 Pfizer Canada Inc.</p>	<h3 style="text-align: center;">STEP 2</h3> <p>Please review each of the descriptions below and rank them from most desirable to least desirable. When ranking these descriptions, please also rank yourself. To make it easier for you to rank these descriptions, consider each description individually and, imagine that it applies to you. Imagine that in all other respects your life is unchanged, including your life span, your friends and family, and your financial situation. You may find it helpful to look at your answers to the questions in Step 1 (pages 2-3) when ranking yourself compared to Descriptions A, B, and C.</p> <p>Please rank the descriptions from 1 to 4 and use each number only once.</p> <p>1 = most desirable, 4 = least desirable</p> <ul style="list-style-type: none"> <input type="checkbox"/> Yourself <input type="checkbox"/> Description A <input type="checkbox"/> Description B <input type="checkbox"/> Description C <p>DESCRIPTION A</p> <ul style="list-style-type: none"> • Most times attains erections that are firm enough and last long enough for sexual activity • A little less sexual drive / interest than usual • Moderately satisfied with self-image (as far as sexuality is concerned) • Occasionally avoids situations that usually could result in sexual activity • Occasionally feels low, irritable or tense • Moderately satisfied with sexual aspects of relationship <p>DESCRIPTION B</p> <ul style="list-style-type: none"> • Occasionally attains erections that are firm enough and last long enough for sexual activity • Significantly less sexual drive / interest than usual • Moderately dissatisfied with self-image (as far as sexuality is concerned) • Often avoids situations that usually could result in sexual activity • Occasionally feels low, irritable or tense • Moderately dissatisfied with sexual aspects of relationship <p>DESCRIPTION C</p> <ul style="list-style-type: none"> • No erections at all • Significantly less sexual drive / interest than usual • Dissatisfied with self-image (as far as sexuality is concerned) • Always avoids situations that usually could result in sexual activity • Often feels low, irritable or tense • Very dissatisfied with sexual aspects of relationship <p>©2005 Pfizer Canada Inc.</p>

The Erectile Function Visual Analog Scale (EF-VAS): a disease-specific utility instrument for the assessment of erectile function

STEP 3

Instructions

Please put the descriptions from the previous page on the scale on the next page. The scale works by showing what you prefer, from most desirable to least desirable. The more desirable you feel a description to be, the closer it should be to the top of the scale. The less preferable or desirable you think a description is, the closer it should be to the bottom.

To help, we have placed one description on the scale for you. The description we have placed is the description of **PERFECT HEALTH**, which will always be the most desirable. Perfect Health describes someone who is completely healthy, both physically and emotionally (including all aspects of erectile function).

Draw a line from each of the boxes to a point on the scale that indicates how desirable each of the descriptions is to you. The description that you chose as least desirable in Step 2 goes at the bottom of the scale (at the zero). If necessary, go back to Step 2 to remind yourself which description you felt was the least desirable.

When placing these descriptions on the scale think about each one individually and **imagine that it applies to you**. **Imagine** that in all other respects your life is unchanged, including your life span, your friends and family, and your financial situation, and **imagine** that you will spend the rest of your life in that particular condition. Do this for each of the descriptions. The distance on the scale between each of these lines should represent how *much* more or less preferable you think each description is when you compare it to the other descriptions.

When you are finished drawing lines from each of the boxes, please write the number from the scale inside each of the boxes. Remember, one of the descriptions must be placed at the bottom of the scale.

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STEP 4

Instructions

During the final step, we have included two new descriptions for you to place on the scale on the next page. Again, the scale works by showing what you prefer, from most desirable to least desirable. The more desirable you feel a description to be, the closer it should be to the top of the scale. The less preferable or desirable you think a description is, the closer it should be to the bottom.

Again, we have placed the description of **PERFECT HEALTH** on the scale as the most desirable. Perfect Health describes someone who is completely healthy, both physically and emotionally (including all aspects of erectile function).

One of the new descriptions that we would like you to place on the scale is **DEAD**. The other new description is **DESCRIPTION D**. This new description (Description D) is shown at the bottom of this page.

When placing these descriptions on the scale think of each one individually and, **imagine that it applies to you**. **Imagine** that in all other respects your life is unchanged, including your life span, your friends and family, and your financial earnings. **Imagine** that you will spend the rest of your life in the condition described. The distance on the scale between each of these lines should represent how much more or less preferable you think each description is when you compare it to the others.

When you are finished drawing lines from each of the boxes, please write the number from the scale inside each of the boxes. Remember, one of the descriptions (the one you think is the least desirable) must be placed at the bottom of the scale (at the zero).

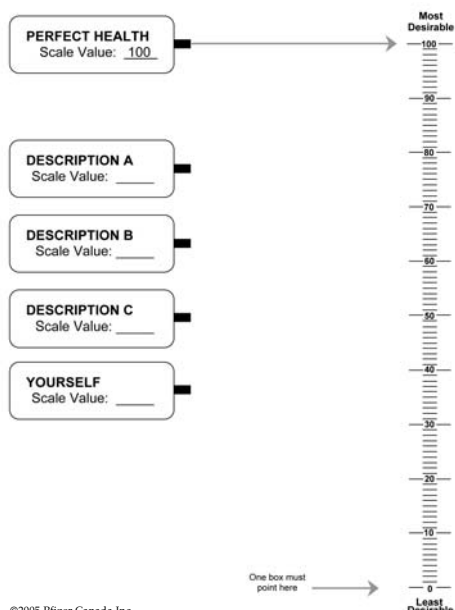
DESCRIPTION D

- Able to see, hear and speak normally
- Requires the help of another person to walk or get around and requires mechanical equipment as well
- Occasionally fretful, angry, irritable, anxious or depressed
- Learns and remembers normally
- Eats, baths, dresses and uses the toilet normally
- Free of pain and discomfort
- Erectile function is normal

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SCALE 1

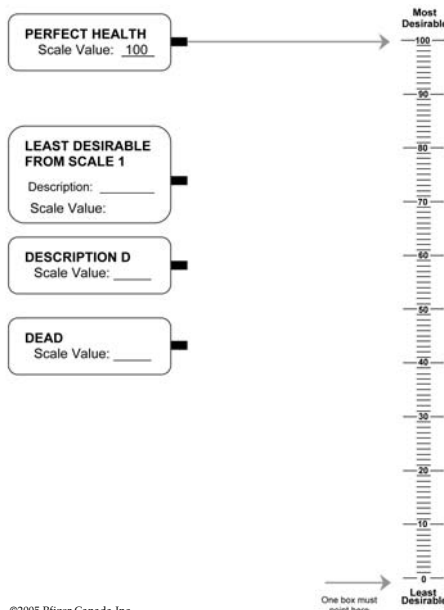
For the series of questions below please think about your experience with erectile dysfunction. Remember that there is no "correct" answer to any of these questions. This exercise will help to determine where you see yourself in terms of the impact of erectile dysfunction on your life. Think about your experience over the past four weeks and place a checkmark (✓) in the box that describes your situation most accurately.



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SCALE 2

Draw a line from each of the boxes to a point on the scale that indicates how desirable each of the descriptions is to you. When you are finished drawing lines from each of the boxes, please write the number from the scale inside each of the boxes. Please indicate whether the description you chose as least desirable from scale 1 is yourself or Description A, B or C. **REMEMBER THE LEAST DESIRABLE DESCRIPTION IN THIS SCALE DOES NOT HAVE TO BE THE SAME ONE YOU CHOSE AS THE LEAST DESIRABLE IN SCALE 1 AND THE BOX SHOULD POINT TO 0.**



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