

## Quantifying Barriers to Improvement of Treatment Satisfaction in Men With Erectile Dysfunction: Use of Person-Item Maps

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### ABSTRACT

**Introduction:** Patient-reported outcomes are a valuable tool used to gauge treatment satisfaction in different conditions, including erectile dysfunction (ED).

**Aim:** To use person-item maps to quantify barriers to improvement of treatment satisfaction in men with ED.

**Methods:** Men 18 to 65 years old with documented ED received sildenafil 50 mg, sildenafil 100 mg, or placebo for 8 weeks in a double-blinded manner. Post hoc analyses were conducted on Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) data (11 items rating treatment satisfaction; each item score range = 0–4).

**Main Outcome Measures:** Person-item maps were developed based on Rasch models. To quantify barriers to improvement of treatment satisfaction, responses to the 11 items of the EDITS questionnaire were dichotomized to indicate improvement (responses of 3 or 4 were combined to a score of 1) vs no change or worsening (responses of 0, 1, or 2 were combined to a score of 0).

**Results:** Analyses were conducted using data from 278 men who completed the EDITS questionnaire at the end of double-blinded treatment. The person-item map indicated that EDITS item 4 (ease of use of treatment) was the easiest barrier to overcome, whereas the most difficult barrier to improvement of treatment satisfaction was EDITS item 2 (degree to which treatment met expectations). Most men in the sildenafil 100-mg group endorsed most EDITS items, consistent with substantial improvement. The sildenafil 50-mg group was similar, but with smaller frequencies for endorsing improvement of the more difficult EDITS items. In contrast, men receiving placebo endorsed mainly the easiest EDITS items, with only a small number of men endorsing the difficult items.

**Conclusion:** A person-item map is a useful means for quantifying barriers to improvement of treatment satisfaction represented by EDITS items in patients with ED.

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**Key Words:** Patient-Reported Outcomes; Treatment Satisfaction; Erectile Dysfunction; Rasch Model; Person-Item Map; Sildenafil

### INTRODUCTION

Erectile dysfunction (ED), defined as the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance, affects up to 52% of men in the United States, with the incidence significantly associated with advancing age.<sup>1</sup> Sildenafil (VIAGRA, Pfizer Inc, New York, NY, USA) was the first oral phosphodiesterase type 5 inhibitor approved by the US

Food and Drug Administration for the treatment of ED based on its efficacy and safety in clinical trials.<sup>2</sup> The recommended starting dose of sildenafil is 50 mg, but the dose can be increased to 100 mg for improved efficacy.<sup>3,4</sup>

A patient-reported outcome (PRO) is a report of a patient's health status that comes directly from the patient, without interpretation of the response by anyone else.<sup>5</sup> PRO measurements are important tools in clinical and research settings to assess various signs and symptoms of health conditions and diseases. Because of the subjective nature of PROs, a PRO measurement must undergo qualitative and psychometric validation of its reliability, validity, and ability to detect differences in scores over time in individuals or groups who have changed with respect to the condition that it is intended to measure.<sup>5</sup> Various PRO measurements have been developed and psychometrically validated to assess erectile function and satisfaction,

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including the International Index of Erectile Function (IIEF),<sup>6</sup> the Sexual Health Inventory for Men,<sup>7</sup> and the Self-Esteem and Relationship Questionnaire.<sup>8–10</sup>

Despite the demonstrated efficacy and safety of ED treatments in clinical trials, many men with ED discontinue treatment in the clinical practice setting.<sup>11</sup> Therefore, a patient's report of treatment satisfaction represents an important component when evaluating the optimal use of treatment and adherence.<sup>12,13</sup> To this end, the 11-item Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) questionnaire was developed, validated as a single-factor measurement of ED treatment satisfaction using classical test theory (CTT) methods, and used in a clinical trial as a measurement of treatment satisfaction in men with ED.<sup>12,14</sup>

In identifying and quantifying barriers to improvement of treatment satisfaction in patients with ED, we applied person-item maps, also known as Wright maps, to depict the relation between the person's underlying level of an attribute (eg, treatment satisfaction) and the difficulty of the items (eg, how difficult it is to overcome barriers to improvement of treatment satisfaction represented by the EDITS items) on the same location scale.<sup>15–17</sup> Person-item maps are based on Rasch analysis models. Rasch analysis has been used to complement CTT methods in the development, validation, and interpretation of PRO measurements.<sup>15–17</sup> A Rasch model is a one-parameter non-linear model (with the one parameter being the difficulty parameter of each item) in which the probability of a positive response by a patient to a particular PRO item is a function of the difference between the patient's level on the attribute (eg, treatment satisfaction) and the difficulty of the item.<sup>16,17</sup>

## AIMS

We aimed to enhance the interpretation of the validated EDITS questionnaire by quantifying barriers to improvement of treatment satisfaction in men with ED by using person-item maps for the 11 items of the EDITS questionnaire.

## METHODS

This post hoc analysis was based on pooled data across treatment groups from a randomized, fixed-dosed, double-blinded, placebo-controlled phase of a multicenter sildenafil trial (NCT00245258).<sup>14</sup> This trial enrolled men 18 to 65 years old from Brazil, Korea, Russia, Spain, and Sweden who were in a stable sexual relationship and had a documented clinical diagnosis of ED (IIEF erectile function domain score  $\leq 25$ ). Men who had taken more than six doses of sildenafil before screening or who were taking nitrates, nitric oxide donors, or  $\alpha$ -blockers were excluded. Exclusion criteria also included hypotension (blood pressure  $< 90/50$  mm Hg), hepatic or severe renal impairment, and significant cardiovascular disease in the past 3 months. All patients randomized to double-blinded treatment started fixed-dose treatment with sildenafil (50 or 100 mg) or matching

placebo (no more than once daily) for 8 weeks. The study protocol was reviewed and approved by the institutional review board or independent ethics committee at each investigative site. All participants provided written informed consent before any study procedures being performed.

Because the Rasch model assumes that all items are measuring a single concept (uni-dimensionality), a confirmatory factor analysis of the EDITS questionnaire was performed. For the confirmatory factor analysis model to fit the data, three criteria were prespecified: (i) Bentler comparative fit index higher than 0.90; (ii) all path coefficients statistically significant ( $P < .05$ ); and (iii) all standardized path coefficients higher than 0.40.<sup>18</sup> Item responsiveness to the underlying estimate of treatment satisfaction on the EDITS questionnaire was assessed with corrected item-to-total correlations, which involves the correlation of each item with the sum of the scores from the remaining items (excluding the item in question).<sup>16</sup> Internal consistency reliability of the EDITS questionnaire was assessed with Cronbach  $\alpha$ .

All statistical analyses were conducted using SAS 9.4M3 (SAS Institute, Cary, NC, USA). Specifically, person-item maps were developed based on Rasch models, which were implemented using PROC IRT in SAS/STAT 14.1 (SAS Institute).

Latent levels of the attribute of interest (eg, treatment satisfaction) are referred to as "abilities" in Rasch terminology. In the Rasch model, item difficulty parameters and the person's latent attribute are determined simultaneously.<sup>16</sup> In the present investigation, items of the EDITS questionnaire are considered barriers that need to be surmounted to improve treatment satisfaction. An item represents a less difficult barrier if it is easier to endorse and a more difficult barrier if it is harder to endorse. In addition, higher ability estimates indicate higher levels of treatment satisfaction.

Difficulty parameters were standardized to have a mean of 0 and an SD of 1 by subtracting the mean of the raw difficulty estimate across items from the raw difficulty estimate of an item and then dividing this subtracted quantity by the SD of the raw difficulty estimates across items. To put attribute parameters on the same scale with difficulty parameters, raw attribute levels also were standardized using the mean and SD of the raw difficulty parameters. These standardized scores are analogous to Z scores and typically range from  $-3$  (least difficult) to  $3$  (most difficult). In this study, a person-item map was created based on estimated treatment satisfaction for patients and estimated item difficulty parameters located on the same scale, where higher scores represent higher levels of treatment satisfaction for persons and higher estimated item difficulty parameters imply greater barriers to overcome for those items.

## MAIN OUTCOME MEASURES

The main outcome measure in this post hoc analysis was the 11-item EDITS (Patient Version) questionnaire (each item score range = 0 [no satisfaction or dissatisfaction] to 4

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