

Development of a New, Adaptable Patient-Reported Outcome Measure of Treatment Satisfaction

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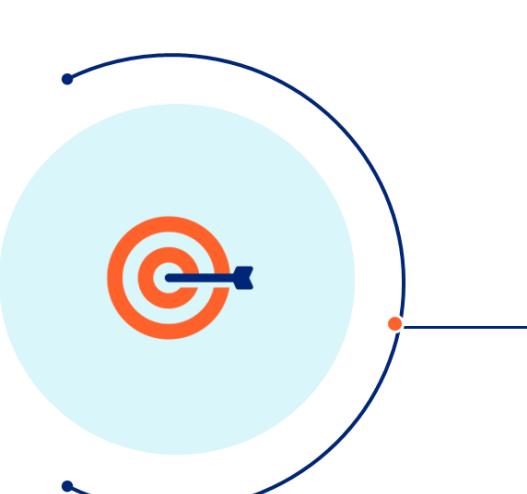
INTRODUCTION

- Treatment satisfaction is a key determinant in evaluating medical intervention efficacy because it encompasses both clinical outcomes and patient experience.^{1,2}
- Patient-reported outcome (PRO) measures of treatment satisfaction provide valuable insights into patient perceptions of treatment effectiveness, convenience, and overall impact.³
- They are increasingly utilized beyond clinical settings to support self-management, shared decision-making, and research.⁴
- They play a critical role in real-world evidence generation, health economics and outcomes research (HEOR), and clinical trials by assessing whether treatments align with patient needs and expectations while minimizing harm.⁵
- However, existing PRO measures vary considerably in scope, reliability, and applicability across different conditions.^{3,6}

OBJECTIVES

Study Aim:

To develop a novel, adaptable PRO measure of treatment satisfaction with clear scoring guidelines, subscales that can be tailored for specialized treatment components, timeframes, side effects, and outcomes, and enhanced change detection.



METHODS

Of the 69 PRO measures identified in a search of the literature, only **four** were generic.^{3,5}

Concerns have been noted for all four, including issues with:

- Content validity
- Change detection (i.e., responsiveness)
- Adaptability
- Scoring complexity
- Applicability to specialized treatments³

To enhance the collection of patient-reported treatment satisfaction data, we developed a comprehensive treatment satisfaction battery featuring adaptable subscales and standardized response scales with clear scoring.

RESULTS

The PRO measure developed for this study includes subscales that assess perceived treatment effectiveness, convenience, and overall impact. Additional details are provided in the table below.

RESULTS CONT.

	Design	Quantitative survey 8 items
	Response scale	1= Strongly disagree 2= Disagree 3= Neither agree nor disagree (neutral) 4= Agree 5= Strongly agree
	Domains	1: Treatment effectiveness 2: Convenience 3: Overall impact
	Sample question – Treatment effectiveness	"I am satisfied with the length of time it took [Treatment Name] to reduce my [Condition Name] symptoms."
	Sample question – Treatment convenience	"I can carry out my normal activities, without disruption, on the days I take [Treatment Name]."
	Sample question – Overall impact of treatment	"Since I started taking [Treatment Name], I have seen improvement in my ability to do daily activities (e.g., reading, driving, completing daily tasks)."

DISCUSSION

- This newly developed scale incorporates the most commonly used subscales for treatment satisfaction PROs while addressing several limitations observed in existing instruments:
 - Content validity** is maintained by capturing all three key dimensions of treatment satisfaction (effectiveness, convenience, impact, as supported by the literature).
 - A 5-point Likert scale with clearly differentiated response options is utilized, which may enhance sensitivity to **change detection** over time.
 - The scale offers flexible timeframes, allowing **adaptation** to treatments with varying onset periods (e.g., 3 days, 1 week, 2 weeks).
 - Domain-level and overall scoring** are supported, enabling calculation of individual domain scores as well as an aggregate treatment satisfaction score.
 - Wording is designed for broad **applicability across therapeutic areas**, ensuring relevance for diverse treatment types.
- Currently, this PRO is being utilized for studies in three therapeutic areas: oncology, dry eye disease, and menopause.
 - However, data from these studies are not yet available to evaluate reliability across these fields.
- Future research should:**
 - Assess the reliability and validity of this PRO instrument by comparing the forthcoming results across studies.
 - Evaluate performance across additional therapeutic areas and varying timeframe to confirm its effectiveness in measuring treatment satisfaction while maintaining adaptability.

CONCLUSION



- Despite their importance in HEOR research, existing PRO measures of treatment satisfaction raise concerns specific to scope, reliability, and applicability across conditions.
- This study offers an alternative that supports timeline and subscale adaptation to suit specialized treatments and conditions.

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