

# Validation of a Questionnaire to Evaluate Simplicity of Diabetes Treatment (SIM-Q)

Kristina S Boye<sup>1</sup>; Louis S Matza<sup>2</sup>; Katelyn N Cutts<sup>2</sup>; Karin S Coyne<sup>2</sup>

<sup>1</sup>Eli Lilly and Company, Indianapolis, IN, USA

<sup>2</sup>Thermo Fisher Scientific, Waltham, MA, USA

Sponsored by Eli Lilly and Company

## OBJECTIVE

- The purpose of this study was to assess the psychometric properties of the SIM-Q.

## CONCLUSIONS

- The SIM-Q is the first validated PRO measure designed to assess treatment simplicity among people treated for T2D. In this study, the SIM-Q demonstrated good reliability and validity in a sample of patients treated for T2D with a range of medications.
- Tirzepatide-treated patients perceived their treatment to be simpler than semaglutide-treated patients. The significant difference between these subgroups suggests that the SIM-Q may be able to distinguish between medication treatment groups.
- The SIM-Q will be useful in clinical trials and observational research to assess and compare the simplicity and complexity of treatments for T2D.



## BACKGROUND

- Treatment for type 2 diabetes (T2D) has evolved over the past two decades, often with newer medication classes offering greater simplicity, which is associated with greater treatment adherence<sup>1,2</sup> and glycemic control.<sup>1,3</sup>
- Due to the association among treatment simplicity, adherence, and outcomes, it is important to consider the patient’s perspective regarding treatment simplicity.
- The Simplicity of Diabates Treatment Questionnaire (SIM-Q) was developed to assess patient perceptions of T2D treatment simplicity. In previous qualitative research with patients treated for T2D, this patient-reported outcome (PRO) measure has demonstrated content validity.<sup>4</sup>

## METHODS

### Study Design

- Patients living with T2D and treated with a range of medications (oral and injectable) were recruited from eight clinical sites in the US.
- At visit 1, all participants completed several PRO measures, including the SIM-Q. Approximately one-third of the participants were randomly selected to participate in a second visit 7±2 days later to assess the test-retest reliability of the SIM-Q.

## RESULTS

### Sample Description

- A total of 250 participants living with T2D in the US were recruited and included in the analyses (mean age = 59.7 years; 54.4% female).

### Item Reduction and Subscale Identification

- Two items (items 9 and 10) were excluded from the subscale identification as they were considered global items.
- Possible redundancies in the SIM-Q items were examined using item-to-item correlations. All item correlations were <0.85 (range: 0.31–0.80; P<0.0001), suggesting that no item should be dropped due to redundancy.
- Exploratory factor analysis found that a one-factor solution (treatment simplicity score) was supported by the Scree plot, with Eigenvalues of 4.35, 0.37, and 0.06 for the first three factors, respectively. The factor loadings for the eight items using oblique rotation ranged from 0.53 to 0.84 (Table 1).

### SIM-Q Scoring

- The SIM-Q yields three scores, all transformed to a 0 to 100 scale, with higher scores indicating greater treatment simplicity: the treatment simplicity scale (items 1–8), a global item assessing simplicity of medication for diabetes (item 9), and a global item assessing simplicity of overall diabetes management (item 10). The eight items in the treatment simplicity scale identify reasons why respondents believe their medication was simple or complex, while the two global items assess respondents’ overall impressions of treatment simplicity.

### Reliability

- Test-retest reliability was evaluated in 37 participants who reported no change in their T2D treatment or emotional health between visits 1 and 2. The SIM-Q demonstrated good test-retest reliability, with intraclass correlation coefficients of 0.80 for the treatment simplicity scale, 0.72 for the global item assessing simplicity of medication for diabetes, and 0.73 for the global item assessing simplicity of overall diabetes management.
- The treatment simplicity scale demonstrated strong internal consistency (Cronbach’s alpha of 0.90).

Figure 1: Simplicity of Diabetes Treatment Questionnaire (SIM-Q)

Please select one response for each item to indicate how you feel today about your current treatment for diabetes. If you take more than one medication for diabetes, you should answer the questions thinking about only one of the medications.

Please complete this questionnaire thinking about: \_\_\_\_\_  
*Name of medication*

Some aspects of diabetes treatment are simple, and others are complex.

How **simple** or **complex** are the following aspects of your current diabetes treatment?

1. Preparing to take the medication (for example, preparing an injection device or getting water for taking tablets)	<input type="checkbox"/> Very complex	<input type="checkbox"/> Complex	<input type="checkbox"/> A little complex	<input type="checkbox"/> Simple	<input type="checkbox"/> Very simple or no preparation needed
2. Taking the medication at the right time	<input type="checkbox"/> Very complex	<input type="checkbox"/> Complex	<input type="checkbox"/> A little complex	<input type="checkbox"/> Simple	<input type="checkbox"/> Very simple or no timing requirements
3. Making sure you take the correct dose of medication each time you take it	<input type="checkbox"/> Very complex	<input type="checkbox"/> Complex	<input type="checkbox"/> A little complex	<input type="checkbox"/> Simple	<input type="checkbox"/> Very simple
4. Taking the medication (including the steps for taking the tablets or giving yourself the injection)	<input type="checkbox"/> Very complex	<input type="checkbox"/> Complex	<input type="checkbox"/> A little complex	<input type="checkbox"/> Simple	<input type="checkbox"/> Very simple
5. Food requirements at the time you take the medication (for example, some medications must be taken either with food, without food, or on an empty stomach)	<input type="checkbox"/> Very complex	<input type="checkbox"/> Complex	<input type="checkbox"/> A little complex	<input type="checkbox"/> Simple	<input type="checkbox"/> Very simple or no food requirements
6. Bringing medication with you when you need to take it away from home	<input type="checkbox"/> Very complex	<input type="checkbox"/> Complex	<input type="checkbox"/> A little complex	<input type="checkbox"/> Simple	<input type="checkbox"/> Very simple or no need to use medication away from home
7. Checking your blood glucose levels on your own	<input type="checkbox"/> Very complex	<input type="checkbox"/> Complex	<input type="checkbox"/> A little complex	<input type="checkbox"/> Simple	<input type="checkbox"/> Very simple or no need to check glucose levels on your own
8. Watching what you eat (for example, eating the right foods and avoiding some foods)	<input type="checkbox"/> Very complex	<input type="checkbox"/> Complex	<input type="checkbox"/> A little complex	<input type="checkbox"/> Simple	<input type="checkbox"/> Very simple

Please answer the following questions about your diabetes treatment:

9. How simple or complex is your medication treatment for diabetes?	<input type="checkbox"/> Very complex	<input type="checkbox"/> Complex	<input type="checkbox"/> A little complex	<input type="checkbox"/> Simple	<input type="checkbox"/> Very simple
10. Overall, how simple or complex is it to manage your diabetes, including medication, checking your blood glucose levels, diet, and any other aspects of diabetes treatment?	<input type="checkbox"/> Very complex	<input type="checkbox"/> Complex	<input type="checkbox"/> A little complex	<input type="checkbox"/> Simple	<input type="checkbox"/> Very simple

### Participants

- Participants were required to meet the following criteria: >18 years of age and a current resident of the US; diagnosed with T2D for at least 6 months; and currently prescribed medication for T2D for at least 4 months.

### Validity

- All correlations with the DTSQs and TRIM-D subscale and total scores were statistically significant (P<0.0001) and moderate to large (Table 2), providing support for convergent validity.
- Known-groups validity was evaluated by categorizing participants based on their responses to item 1 from the TRIM-D (“satisfaction with ease and convenience of medication”). Participants who reported greater satisfaction on this TRIM-D item reported greater simplicity on the SIM-Q (all P<0.0001) (Table 3).
- Participants treated with tirzepatide had significantly greater mean scores on the global item assessing simplicity of medication for diabetes (P=0.014) and the global item assessing simplicity of overall diabetes management (P=0.018) than participants treated with injectable semaglutide (Figure 2).

Table 1: SIM-Q Exploratory Factor Analysis (N = 250)

SIM-Q <sup>a</sup>	Exploratory Factor Analysis <sup>b</sup>	
	Factor 1	
Item 1: Preparing to take	0.78	
Item 2: Taking at right time	0.84	
Item 3: Making sure take correct dose	0.83	
Item 4: Taking medication	0.83	
Item 5: Food requirements	0.69	
Item 6: Bringing medication	0.68	
Item 7: Checking blood glucose levels	0.66	
Item 8: Watching what eat	0.53	

Abbreviation: SIM-Q = Simplicity of Diabetes Treatment Questionnaire

<sup>a</sup> The SIM-Q asks participants to think about how simple or complex their current diabetes medication is: “How simple or complex are the following aspects of your current diabetes treatment” on a scale ranging from “very complex” to “very simple or no preparation needed.”

<sup>b</sup> An exploratory factor analysis (oblique rotation) was conducted with a one-factor solution on the first eight items: Factor 1 is the treatment simplicity score.

Table 2: Construct Validity of the SIM-Q<sup>a</sup>

Measure	Treatment Simplicity Scale	Global Item Assessing Simplicity of Medication for Diabetes <sup>b</sup>	Global Item Assessing Simplicity of Overall Diabetes Management <sup>b</sup>
DTSQs Score	0.34****	0.38****	0.40****
TRIM-D Treatment Burden Subscale	0.57****	0.46****	0.51****
TRIM-D Daily Life Subscale	0.32****	0.36****	0.33****
TRIM-D Diabetes Management Subscale	0.37****	0.33****	0.43****
TRIM-D Compliance Subscale	0.40****	0.31****	0.41****
TRIM-D Total Score	0.56****	0.46****	0.57****

Abbreviations: DTSQs = Diabetes Treatment Satisfaction Questionnaire-Status; TRIM-D = Treatment Related Impact Measure – Diabetes

<sup>a</sup> Spearman rank-order correlation coefficients: \*P<0.05, \*\*P<0.01, \*\*\*P<0.001, \*\*\*\*P<0.0001

<sup>b</sup> One participant had a missing response for the global item assessing simplicity of medication for diabetes; three participants had a missing response for the global item assessing simplicity of overall diabetes management.

## Measures

- SIM-Q:** A 10-item PRO measure developed to assess the simplicity and complexity of current treatment for T2D. Respondents rate the simplicity or complexity of eight treatment attributes on a five-point scale ranging from “very complex” to “very simple.” There are also two global items.<sup>4</sup> Higher scores indicate greater simplicity (Figure 1).
- Treatment Related Impact Measure – Diabetes (TRIM-D):** A 28-item PRO measure assessing five domains: treatment burden, daily life, diabetes management, compliance, and psychological health. Higher scores indicate better health states.<sup>5</sup>
- Diabetes Treatment Satisfaction Questionnaire – Status (DTSQs):** An eight-item PRO measure developed to assess satisfaction with their diabetes treatment. Six items measure treatment satisfaction, and the sum of these items produces a DTSQs score. Higher scores indicate greater satisfaction with treatment.<sup>6</sup>
- 7 tests were used to examine differences in the SIM-Q between participants treated with tirzepatide and those treated with injectable semaglutide.

## Analyses

- Analyses focused on item-level performance, exploratory factor analysis for subscale identification, internal consistency reliability, test-retest reliability, construct validity, known-groups validity, and development of a scoring algorithm.
- 7 tests were used to examine differences in the SIM-Q between participants treated with tirzepatide and those treated with injectable semaglutide.

Table 3: Known-groups Validity of SIM-Q By TRIM-D Item 1a<sup>a</sup>

SIM-Q <sup>b</sup>	Extremely satisfied (N=119) Mean (SD)	Very satisfied (N=93) Mean (SD)	A little/Somewhat satisfied (N=34) Mean (SD)	Overall F Value	P-value	Significant Pairwise Comparisons <sup>c</sup>
Treatment Simplicity Scale Score	85.21 (15.57)	78.49 (17.13)	65.81 (15.65)	19.63***	<0.0001	A*, B***, C***
Simplicity of Medication Treatment for Diabetes Score	(N=118) 87.71 (18.12)	76.34 (22.23)	61.76 (25.55)	22.44***	<0.0001	A***, B***, C**
Overall Diabetes Management Score	(N=117) 76.07 (23.76)	(N=92) 62.77 (23.00)	47.79 (21.64)	22.13***	<0.0001	A***, B***, C**

<sup>a</sup> TRIM-D item 1a asks participants: “How satisfied or dissatisfied have you been with the ease and convenience of your medication?”

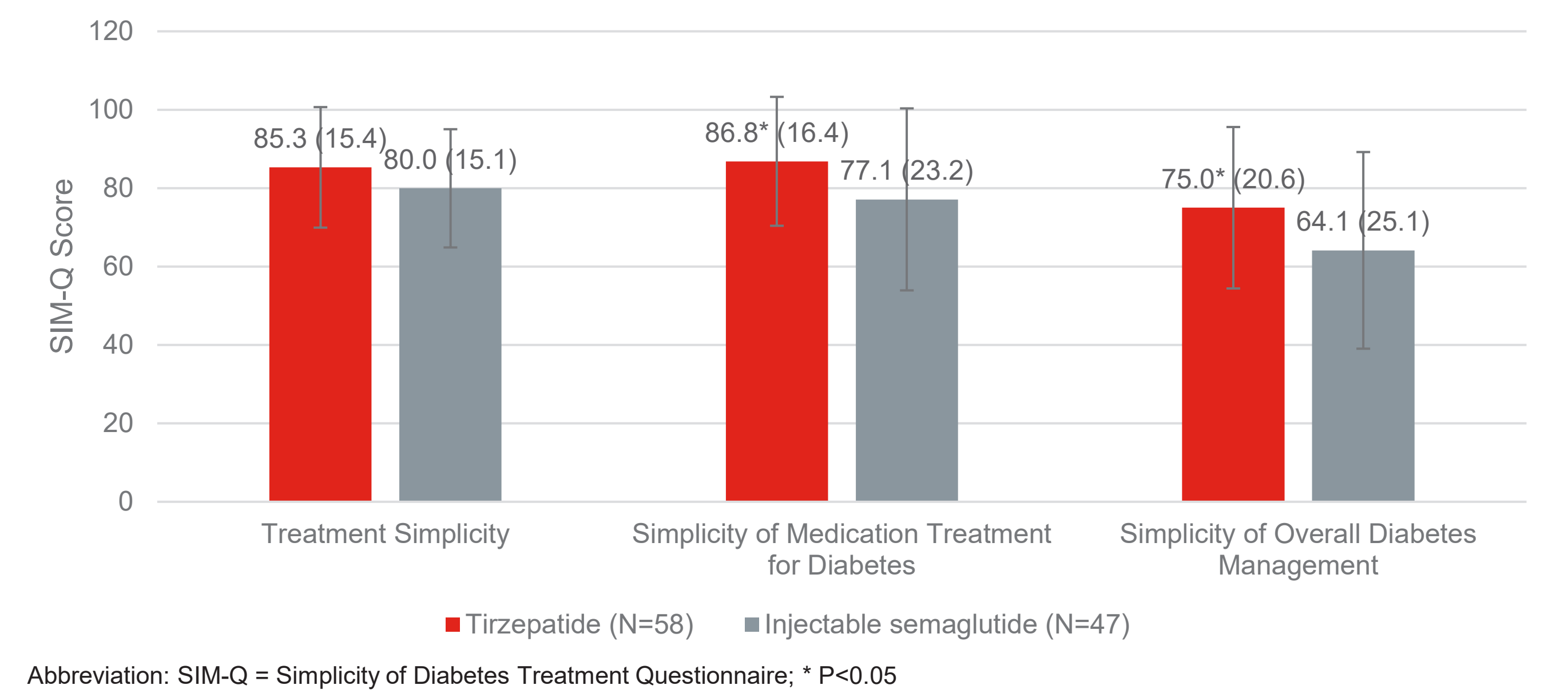
<sup>b</sup> SIM-Q subscale scores could not be calculated for three participants due to missing data.

<sup>c</sup> Scheffé post hoc pairwise comparisons: A: Extremely satisfied vs Very satisfied; B: Extremely satisfied vs A little/Somewhat satisfied; C: Very satisfied vs A little/Somewhat satisfied

\*P<0.05; \*\*P<0.01; \*\*\*P<0.001

Note: Participants who selected “not at all satisfied” were removed from the analyses due to small sample size (n=2).

Figure 2: Tirzepatide-treated Participants vs. Injectable Semaglutide-treated Participants by SIM-Q Scores



## Limitations

- The sample size was relatively small for subgroups used in the analyses focusing on test-retest reliability and comparisons between treatment groups.

**References**

- Ayele AA, et al. *BMJ Open Diabetes Res Care*. 2019;7(1):e000685.
- de Vries ST, et al. *J Psychosom Res*. 2014;76(2):134-138.
- Abdelaziz TS, Sadek KM. *Rom J Intern Med*. 2019;57(1):23-29.
- Stewart KD, et al. *J Patient Rep Outcomes*. 2023;7(1):89.
- Brod M, et al. *Health Qual Life Outcomes*. 2009;7:83.
- Bradley C, Lewis KS. *Diabet Med*. 1990;7(5):445-451.

**Disclosures:** Louis Matza, Katelyn N Cutts, and Karin S Coyne are employees of PPD™ Evidera™ Patient-Centered Research, Thermo Fisher Scientific, who received funding from Lilly to conduct this study.

For permission to reproduce or use the SIM-Q, please contact [copyright@lilly.com](mailto:copyright@lilly.com). After permission is obtained, there is no fee for use.