PCR56

Development of a Questionnaire to Assess the Emotional Impact of Treatment for Type 2 Diabetes

Katie D. Stewart,[1] Louis S. Matza,[1] and Kristina S. Boye[2]

[1]Patient-Centered Research, Evidera, Bethesda, MD, USA; [2]Eli Lilly and Company, Indianapolis, IN, USA

BACKGROUND

- Patients receiving treatment for type 2 diabetes (T2D) may experience an emotional impact associated with treatment-related changes.[1] Treatments associated with significant clinical benefits like glycemic control and weight loss may be associated with emotional impact.[2]
- Generic and disease-specific instruments have been used to assess the impact of T2D on quality of life, and several of these instruments include items on emotional status.[3-5] However, no existing questionnaire provides a detailed assessment of the emotional impact of T2D and its treatment.

OBJECTIVE

- **This qualitative study was designed to explore the emotional impact of treatment for T2D and to support the development of a questionnaire to assess the emotional impact of treatment for T2D.**

KEY RESULTS

Table 2. Impact on Emotions Reported by Participants in Exit Interviews Following Treatment with Tirzepatide in the SURPASS Trials

	Frequency (%) of Respondents with Each Type of Emotional Impact	
	Positive	**Negative**
Confidence	23 (82.1%)	-
Hope	23 (82.1%)	-
Self-esteem	23 (82.1%)	-
Relief	22 (78.6%)	1 (3.6%)
Optimism	21 (75.0%)	-
Sense of control	21 (75.0%)	1 (3.6%)
Worry/anxiety	19 (67.9%)	1 (3.6%)
Happy	15 (53.6%)	-
Motivation	15 (53.6%)	-
Frustration	13 (46.4%)	2 (7.1%)
Fear	9 (32.1%)	1 (3.6%)
Depressed	3 (10.7%)	1 (3.6%)

Figure 1. Emotional Impact of Diabetes Treatment Questionnaire - Status

(In the instructions, text in brackets may be selected based on the design and purpose of the study or situation in which the questionnaire is being used.)

When completing the items below, please **think about how your [*current diabetes medication; diabetes study medication; etc.*] has affected you emotionally.** [Please think about your emotions related to the diabetes study medication, NOT your feelings about losing access to the study medication after the study.]

Please select **one response** for each item to indicate how you have **felt in the past week** because of your [*current diabetes medication; diabetes study medication; etc.*].

	Because of your [medication], how often have you felt the following:				
	Never	**Rarely**	**Sometimes**	**Often**	**Almost Always**
1. Hopeful	☐	☐	☐	☐	☐
2. Optimistic	☐	☐	☐	☐	☐
3. Happy	☐	☐	☐	☐	☐
4. Relieved	☐	☐	☐	☐	☐
5. Self-Confident	☐	☐	☐	☐	☐
6. Good about myself	☐	☐	☐	☐	☐
7. Motivated	☐	☐	☐	☐	☐
8. Energetic	☐	☐	☐	☐	☐

	Because of your [medication], how often have you felt the following:				
	Never	**Rarely**	**Sometimes**	**Often**	**Almost Always**
9. In control of my diabetes	☐	☐	☐	☐	☐
10. In control of my eating	☐	☐	☐	☐	☐
11. In control of my weight	☐	☐	☐	☐	☐
12. Fearful	☐	☐	☐	☐	☐
13. Frustrated	☐	☐	☐	☐	☐
14. Worried	☐	☐	☐	☐	☐

Copyright © 2021 Eli Lilly and Company
The Emotional Impact of Diabetes Treatment Questionnaire–Status (EIDTQs) is copyrighted by Eli Lilly and Company.
For permission to reproduce or use the EIDTQs, please contact copyright@lilly.com.

CONCLUSIONS

- The EIDTQ-Status and Comparison measures may be useful for evaluating the emotional impact of treatment for T2D. The questionnaire instructions can be customized based on the design and purpose of the study or situation in which the questionnaire is being used.
- The qualitative data gathered in this study supports the content validity of the EIDTQ-Status and EIDTQ-Comparison.
- The next step in this line of research will be to administer these instruments to larger samples of patients so that psychometric properties can be examined, and a scoring algorithm can be derived.

METHODS

Key Eligibility Criteria

- **Inclusion criteria for both phases**: Willing and able to provide informed consent, currently a US resident, at least 18 years of age, diagnosed with T2D.
- **Additional criteria for concept elicitation phase**: Treated with tirzepatide in SURPASS-2 or SURPASS-3 trial and completed the four-week follow-up safety period.
- **Additional criteria for cognitive interview phase**: Currently receiving prescription medication for T2D.

Study Design

- Concept elicitation on the emotional impact of diabetes treatment was conducted through exit interviews with 28 patients with T2D participating in the SURPASS-2 and SURPASS-3 trials for tirzepatide.
- Results of the concept elicitation interviews were used to develop two questionnaires (The Emotional Impact of Diabetes Treatment Questionnaires) that were evaluated in cognitive interviews with 20 patients with T2D.

Study Design (cont)

- Cognitive interview participants were asked to complete the EIDTQ-Status and EIDTQ-Comparison and provide feedback on the instructions, items, and response options.
- Interviews were recorded, transcribed, and analyzed following a content analysis approach using ATLAS.ti.

Emotional Impact of Diabetes Treatment Questionnaires (EIDTQ)

- The EIDTQ-Status is a 14-item measure developed to assess the emotional impact of treatment for T2D (Figure 1). This measure asks participants to think about how their diabetes medication has affected them emotionally and rate the frequency of experiencing emotions due to their diabetes medication on a 5-point scale ranging from 'never' to 'almost always.'
- The EIDTQ-Comparison is a 14-item measure developed to compare the emotional impact of two treatments for T2D. This measure asks participants to think about how one diabetes treatment has affected them emotionally compared to another treatment and rate emotions on a 5-point scale ranging from 'much more' to 'much less.'

Table 1. Demographic and Clinical Characteristics

Characteristics	Concept Elicitation N=28	Cognitive Interviews N=20
Age, years (mean, SD)	57.6 (10.0)	58.3 (9.5)
Gender (n, %)		
Male	10 (35.7%)	8 (40.0%)
Female	18 (64.3%)	12 (60.0%)
Race (n, %)		
Black or African American	7 (25.0%)	2 (10.0%)
Native Hawaiian or other Pacific Islander	1 (3.6%)	-
White	16 (57.1%)	17 (85.0%)
Multiple[1]	1 (3.6%)	-
Other	3 (10.7%)	1 (5.0%)
Duration of diabetes diagnosis (years), mean (SD)	10.3 (5.0)	11.8 (6.4)
BMI, mean kg/m^2 (SD)	33.0 (6.9)	33.3 (8.6)
Current treatment for T2D[2]		
Oral medication only	23 (82.1%)	11 (55.0%)
Injectable GLP-1 RA	-	1 (5.0%)
Oral and insulin	-	3 (15.0%)
Oral and injectable GLP-1 RA	1 (3.6%)	5 (25.0%)
Oral and injectable medication (unknown)	3 (10.7%)	-

Abbreviations: BMI = body mass index; GLP-1 = glucagon-like peptide-1; RA = receptor agonist; SD = standard deviation; T2D = type 2 diabetes.

[1] Multiple includes: American Indian or Alaska Native + White (n=1).

[2] Current medication was not reported for one participant in the concept elicitation phase

RESULTS

Concept Elicitation

- Concept elicitation interviews were conducted with 28 patients (Table 1).
- Most patients reported positive changes in emotions associated with their study medication. Negative emotional impact was less commonly reported (Table 2).

Cognitive Interviews

- Cognitive interviews were conducted with 20 patients with T2D (Table 1).
- Nine of the first 15 participants completing the first two versions of the EIDTQ-Status demonstrated difficulty understanding that their responses on the questionnaire should be related to the impact of their diabetes treatment.
- Seven of the first 15 participants also had difficulty comparing two diabetes treatments when completing the EIDTQ-Comparison.

Cognitive Interviews (cont)

- The draft questionnaires were updated several times during the cognitive interview study. For example, the instructions were shortened to make them easier to understand, and the item stem was revised to focus on the relationship between emotions and diabetes treatment.
- Participants in the final set of interviews understood the questionnaire items and instructions as intended and they were able to complete the final version of the EIDTQ-Status and Comparison without difficulty.

REFERENCES

1. Reis ACD, et al. *Rev Assoc Med Bras (1992)*. 2019;65(12):1464-1469.
2. Svedbo Engstrom M, et al. *Health Qual Life Outcomes.* 2019;17(1):141.
3. Janssen MF, et al. *Diabet Med*. 2011;28(4):395-413.
4. Peyrot M, et al. *Diabetes Res Clin Pract*. 2013;99(2):174-184.
5. Zurita-Cruz JN, et al. *Health Qual Life Outcomes*. 2018;16(1):94.

DISCLOSURES

This study was funded by Eli Lilly and Company (Indianapolis, IN).

Scan or click the QR code or use this URL (https://lillyscience.lilly.com/congress/ispor2022) for a list of all Lilly content presented at the congress.

Other company and product names are trademarks of their respective owners.

International Society for Pharmacoeconomics and Outcomes Research (ISPOR); National Harbor, Maryland; 15 – 18 May 2022

Sponsored by Eli Lilly and Company