

Psychometric evaluation of Diabetes Treatment Satisfaction Questionnaire (DTSQs) in eight languages



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1) Background

- Trials of newly developed drugs now usually include psychological outcome measures in parallel with clinical outcome measures. The DTSQ is a measure of satisfaction with diabetes treatment regimens. Designed and developed in the 1980s^{1,2}, the DTSQ is now in a form suitable for people with either Type 1 or 2 diabetes mellitus³ and is widely used in clinical trials^{3,4}.
- Multinational drug companies operating in a global environment need psychological outcome measures in several languages to allow for combined analyses of data across countries and languages, in parallel with the clinical data. The present research was conducted in the context of a series of clinical trials to develop a new longer-acting insulin, insulin glargine. The DTSQ was already available in several translations and recommended for use in the St Vincent Declaration Action Programme for Diabetes in Europe⁵. The present work included further translations and psychometric assessments of all 8 language versions used.

2) Objectives

- To confirm the psychometric properties of the 8-item DTSQ status version (DTSQs) in:
 - ↳ English (for the UK)
 - ↳ French (France and French-speaking Switzerland)
 - ↳ German (for Germany, Austria and German-speaking Switzerland)
 - ↳ Swedish (Sweden and Finland)
- To evaluate:
 - ↳ English (for S.Africa and USA)
 - ↳ Dutch (new translation)
 - ↳ Danish (new translation)
 - ↳ Norwegian (new translation)
 - ↳ Finnish (new translation)

3) Method: Design & Participants

- 2,223 participants with Type 1 or Type 2 diabetes treated with insulin or poorly controlled on sulphonylureas at baseline who started using insulin within the trial.
- Five multinational, open-label, Phase II and III randomised-controlled trials to evaluate safety and efficacy of longer-acting basal insulin glargine, compared with commonly used standard basal insulin (NPH):
 - ↳ Three trials in Europe and South Africa :
 - two for patients with Type 1 diabetes
 - one for patients with Type 2 diabetes
 - ↳ Two trials in USA :
 - one for patients with Type 1 diabetes
 - one for patients with Type 2 diabetes
- Conducted by Hoechst Marion Roussel (now Aventis)

4) Method: Psychometrics

In the English version of the DTSQ (8 items) the 6 satisfaction items are summed and used as a treatment Satisfaction score (items 1, 4-8). Items 2 and 3 are concerned with perceived frequency of hyper- and hypoglycaemia and these are treated individually. Psychometric analyses were carried out primarily on baseline data from the trials to assess the psychometric properties of each language compared with those of the reference language (English for the UK).

- Exploratory Factor Analysis on all languages
 - ↳ Using varimax rotation
 - Confirmatory Factor Analysis on the larger USA samples
 - Reliability Analysis including Cronbach's alpha
- In addition follow-up data were used for:
- Sensitivity to change in treatment Satisfaction using Analysis of Covariance
 - ↳ The example given here is from the Phase 3 European Type 1 study

The Diabetes Treatment Satisfaction Questionnaire (DTSQs)

The following questions are concerned with the treatment for your diabetes (including insulin, tablets and/or diet) and your experience over the past few weeks. Please answer each question by circling a number on each of the scales.

- How satisfied are you with your current treatment?
very satisfied 6 5 4 3 2 1 0 very dissatisfied
- How often have you felt that your blood sugars have been unacceptably high recently?
most of the time 6 5 4 3 2 1 0 none of the time
- How often have you felt that your blood sugars have been unacceptably low recently?
most of the time 6 5 4 3 2 1 0 none of the time
- How convenient have you been finding your treatment to be recently?
very convenient 6 5 4 3 2 1 0 very inconvenient
- How flexible have you been finding your treatment to be recently?
very flexible 6 5 4 3 2 1 0 very inflexible
- How satisfied are you with your understanding of your diabetes?
very satisfied 6 5 4 3 2 1 0 very dissatisfied
- Would you recommend this form of treatment to someone else with your kind of diabetes?
Yes, I would definitely recommend the treatment 6 5 4 3 2 1 0 No, I would definitely not recommend the treatment
- How satisfied would you be to continue with your present form of treatment?
very satisfied 6 5 4 3 2 1 0 very dissatisfied

Please make sure that you have circled one number on each of the scales.

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Table 1: Example of the most commonly seen structure (taken from the Phase 3 study of English-speaking patients with Type 1 diabetes in the USA)

Item	DTSQ Factor Structure (n = 486)				
	Unforced		Forced 3-factor		
	Factor 1 (Satisfact ⁿ)	Factor 2 (PerCBGC)	Factor 1 (Satisfact ⁿ)	Factor 2 (P.Hypers)	Factor 3 (P.Hypos)
1 Satisfied	.749	-.192	.735	-.260	-.049
2 Hyperglycaemia	-.167	.627	-.099	.976	.043
3 Hypoglycaemia	.074	.785	.032	.039	.958
4 Convenient	.792	-.087	.787	-.126	-.020
5 Flexible	.793	.023	.795	-.001	.023
6 Understand	.436	-.274	.452	-.022	-.331
7 Recommend	.785	.017	.796	.081	-.047
8 Continue	.832	-.074	.828	-.109	-.017

Confirmatory factory analysis on a two-factor structure: Goodness of Fit Index GFI = 0.954

Item	Factor Analysis			
	Unforced Satisfaction Loadings on Factor 1			
	English UK & S.Africa (n = 118)	English USA Type 1 only (n = 486)	English USA Type 2 only (n = 469)	German Germany, Austria & Switzerland (n = 398)
1 Satisfied	.692	.749	.813	.651
4 Convenient	.756	.792	.810	.728
5 Flexible	.739	.793	.731	.777
6 Understand	.541	.436	.516	.623
7 Recommend	.720	.785	.799	.728
8 Continue	.672	.832	.843	.734

Table 3: Forced 1-factor Satisfaction loadings in those languages with imperfect unforced factor structure

Factor Analysis						
Forced 1-factor Satisfaction Loadings						
	French (n = 100)	Dutch (n = 100)	Danish (n = 89)	Norwegian (n = 61)	Swedish (n = 122)	Finnish (n = 95)
1 Satisfied	.850	.786	.858	.869	.768	.832
4 Convenient	.686	.704	.708	.862	.702	.588
5 Flexible	.701	.655	.844	.784	.678	.748
6 Understand	.467	.326	.446	.411	.435	.460
7 Recommend	.743	.714	.685	.888	.704	.711
8 Continue	.839	.765	.793	.776	.838	.715

Table 4: Reliability analyses for the 6-item treatment Satisfaction score for all languages / language subsets

Reliability: Cronbach's alpha				
Language	Country	n	alpha	alpha if Q.6 deleted
English	UK, South Africa	120	.795	.802
French	France, Switzerland	101	.827	.848
German	Germany, Austria, Switzerland	406	.805	.790
Dutch	Netherlands	100	.747	.791
Danish	Denmark	91	.813	.841
Norwegian	Norway	61	.865	.894
Swedish	Sweden, Finland	127	.801	.812
Finnish	Finland	96	.778	.782
English	USA (Type 1 only)	488	.838	.856
English	USA (Type 2 only)	473	.852	.867

Figure 1: Randomised controlled trial of long-acting insulin glargine compared with NPH human basal insulin⁶

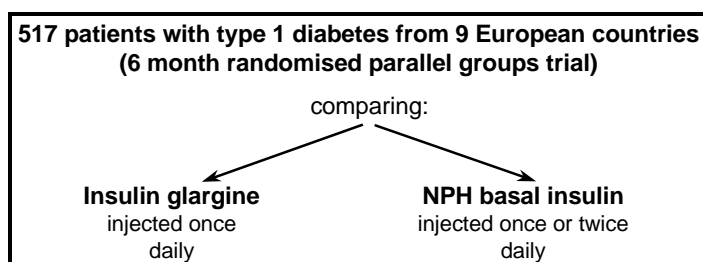
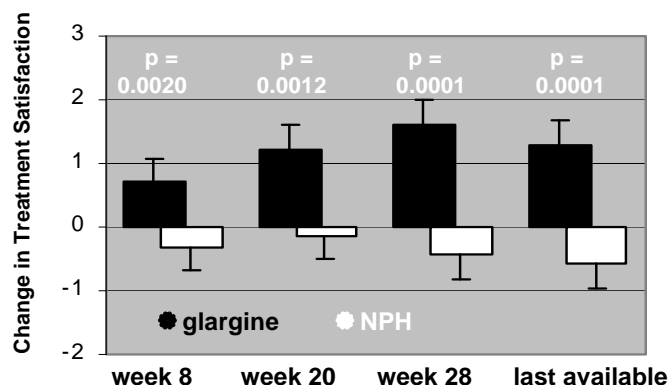


Figure 2: Change in Treatment Satisfaction⁶



6) Summary and Conclusions

- The structure was entirely as expected in English and German and with the exception of Q.6, it was also as expected in most other languages.
- In the Dutch and Finnish versions, where the Ns were borderline, the structure was less clear.
- Forced 1-factor showed all *Satisfaction* items to load >0.4 in all languages, with the exception of Q.6 in Dutch.
- Reliabilities are consistently very good across all languages.
- Item 6 (*Understanding*) is the only item to detract from the internal consistency and does so for all languages. However the effect is small and the item compensates by broadening the content of the measure.
- Since within-language sample sizes are smaller than desired in some cases and no problems are seen where samples are large, it is not recommended that any items be dropped or changed. Further evaluation of the Dutch and Finnish in larger samples is required.
- Data from the Phase 3 European Type 1 trial, using all languages, showed highly significant sensitivity to change⁶.
- The DTSQ and its translations are recommended for use in other trials.

References

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Other versions of the DTSQ

- Other condition-specific treatment satisfaction questionnaires are now available for use with:
 - ↳ Renal disease (the RTSQ)
 - ↳ HIV (the HIVTSQ)
 - ↳ Genital herpes (GHTSQ)
 - ↳ Satisfaction with Antidepressant Medication (SAMQ)
- DTSQ change version (DTSQc) for use when satisfaction is high at baseline, in order to increase sensitivity to change.

Enquiries, including access to questionnaires and data management guidelines:

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A c k n o w l e d g e m e n t s

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