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# Linguistic and Psychometric Validation of the Diabetes-Specific Quality-of-Life Scale in U.K. English for Adults With Type 1 Diabetes

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**OBJECTIVE**—To develop a linguistically and psychometrically validated U.K. English (U.K./Ireland) version of the Diabetes-Specific Quality-of-Life Scale (DSQOLS) for adults with type 1 diabetes.

**RESEARCH DESIGN AND METHODS**—We conducted independent forward and backward translation of the validated German DSQOLS. An iterative interview study with health professionals ( $n = 3$ ) and adults with type 1 diabetes ( $n = 8$ ) established linguistic validity. The DSQOLS was included in three Dose Adjustment for Normal Eating (DAFNE) studies (total  $N = 1,071$ ). Exploratory factor analysis (EFA) was undertaken to examine questionnaire structure. Concurrent and discriminant validity, internal consistency, and reliability were assessed.

**RESULTS**—EFA indicated a six-factor structure for the DSQOLS (social aspects, fear of hypoglycemia, dietary restrictions, physical complaints, anxiety about the future, and daily hassles). High internal consistency reliability was found for these factors and the weighted treatment satisfaction scale ( $\alpha = 0.85-0.94$ ). All subscales were moderately, positively correlated with the Audit of Diabetes-Dependent Quality-of-Life (ADDQoL) measure, demonstrating evidence of concurrent validity. Lower DSQOLS subscale scores [indicating impaired quality of life (QoL)] were associated with the presence of diabetes-related complications.

**CONCLUSIONS**—The DSQOLS captures the impact of detailed aspects of modern type 1 diabetes management (e.g., carbohydrate counting and flexible insulin dose adjustment) that are now routine in many parts of the U.K. and Ireland. The U.K. English version of the DSQOLS offers a valuable tool for assessing the impact of treatment approaches on QoL in adults with type 1 diabetes.

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For people living with type 1 diabetes, the daily challenge is to strike an acceptable balance of self-care activities to achieve optimal glycemic outcomes with-

out damaging quality of life (QoL). Glycemic control is objective, easy to measure, and emphasized in clinical studies. QoL is subjective, poses significant measurement

challenges, and is often forgotten or ignored. Over 10 years ago, a prominent U.S. psychologist urged that behavioral outcomes in diabetes studies be accorded the same importance as biomedical outcomes (1). More recently, the U.K. National Institute for Health and Clinical Excellence has recognized QoL as an important treatment goal in diabetes (2). The need to assess patient-reported outcome measures has been recognized by the U.K. Department of Health with, for example, introduction of the requirement to capture patient-reported assessment of health before and after certain elective procedures (3). The U.S. Food and Drug Administration has also issued definitive guidance promoting the use of patient-reported outcome measures in medicinal labeling claims (4).

Diabetes self-management education programs have been part of routine care in countries like the U.S., Germany, and Austria for several decades but introduced in the U.K. and Ireland only in the past decade. Their importance has been endorsed in National Institute for Health and Clinical Excellence guidance on patient education models (2) and through the National Service Framework for Diabetes in the U.K. (5,6). A joint Department of Health, National Health Service, and Diabetes UK initiative provided a tool kit for commissioners to evaluate diabetes education provision within their services (7). This report fell short of offering guidance on the evaluation of diabetes education at the individual patient level. A recent national consensus report from Australia addressed this issue and provided guidance on how to evaluate diabetes education across a spectrum of outcomes including knowledge, self-management, self-determination, and psychological adjustment, with the latter including QoL (8).

The Dose Adjustment for Normal Eating (DAFNE) program is a collaborative of clinicians, social scientists, and health economists actively delivering

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and evaluating skill-based structured education promoting flexible, intensive insulin therapy for adults with type 1 diabetes. The collaborative has identified a need to improve the existing approach to assessing outcomes of diabetes structured education.

In a recent review of English-language instruments commonly used to assess QoL, the authors caution against the frequent oversimplification that all psychosocial assessments measure QoL; some do, but others quantify related but separate constructs such as treatment satisfaction, psychological well-being, and health status (9). A number of instruments have been developed to measure the impact of diabetes on QoL: the Audit of Diabetes-Dependent Quality-of-Life (ADDQoL) (10), the Diabetes Quality-of-Life (DQOL) scale (11), and the Diabetes-Specific Quality-of-Life Scale (DSQOLS) (12). Used in the original DAFNE trial (13), the ADDQoL was sensitive to the benefits of flexible, intensive insulin therapy but considered too lengthy for future routine use, and the use of hypothetical scenarios was considered too complex for some respondents (9,14). The DQOL has been used widely with somewhat disappointing results. In particular, the reported lack of difference between intensified and conventional treatment groups in the Diabetes Control and Complications Trial (15) is likely to be “attributable to the limitations of the measure rather than to any real lack of impact of intensification of treatment on QoL” (16). Over 20 years old, many of the items are outdated now, and we have found, in our recent experience of using it in the U.K., that respondents find it frustrating to complete. Recognizing that the DQOL was low on sensitivity and discriminant validity, Bott et al. (12) designed the DSQOLS. It was designed specifically for people with type 1 diabetes using modern insulin regimens and has proven sensitive to differences between various insulin regimens, as well as between conventional insulin treatment and insulin pump therapy (12,17).

The original version of the DSQOLS was developed and validated in German (12). In this report, we describe the linguistic and psychometric validation of a U.K. English-language version of the DSQOLS. The performance of the questionnaire was assessed using data from three groups of adults with type 1 diabetes undertaking DAFNE education.

## RESEARCH DESIGN AND METHODS

### DSQOLS

The original 64-item DSQOLS was designed in Germany specifically for people with type 1 diabetes (12). It includes 44 burden items measuring the impact of diabetes on “social relations,” “leisure time flexibility,” “diet restrictions,” “physical complaints,” “daily hassles,” and “worries about the future.” Respondents are asked to rate the extent to which each of the statements meets their “point of view” on a 6-point Likert scale: from “perfectly” to “not at all.” A further 10 items measure treatment satisfaction (on a 6-point scale from “very satisfied” to “very dissatisfied”), and 10 more assess the personal importance of treatment goals on a 6-point Likert scale from “very important” to “totally unimportant.” The design of the DSQOLS was based on interviews with adults with type 1 diabetes, but its precise development and item generation were not described in detail (12). Psychometric validation of the original DSQOLS was undertaken using data from a sample of 657 people with type 1 diabetes attending general practice in the North Rhine region of Germany (12). A systematic review of patient-completed health outcome measures for diabetes concluded that there was good evidence for the reliability and internal and external construct validity of the German-language version of DSQOLS (18).

The original German-language version was later revised after further unpublished validation work (U. Bott, unpublished observations). Eleven items were retained without modification, but 27 items were amended slightly to aid interpretation (e.g., “diabetes restrains my future plans” amended to “diabetes interferes with my future plans”). Six items were omitted because of low item-scale correlations in their original analyses or weak factor loadings (<0.3). Nineteen additional items were introduced, 11 of which to assess fear of hypoglycemia. Thus, this revised version of the DSQOLS includes a total of 77 items, comprising 10 individual treatment goal items, 10 treatment-satisfaction items, and 57 diabetes-specific burden items. The validation work presented here is based upon this revised version of the German DSQOLS.

### Translation and linguistic validation of the DSQOLS into English (U.K. and Ireland)

Although the original DSQOLS was validated in German and not English, it was first described in an English-language journal (12) in which an English version was presented, though this was not a robust translation and was not linguistically validated. The DSQOLS has not, to our knowledge, been translated into any other languages. The revised German DSQOLS and its unauthorized English translation were obtained from the authors. An independent translator, bilingual in German and English, who had not seen the questionnaire, carried out a second forward translation from German into U.K. English. Following international guidelines for translation and cultural adaptation of questionnaires (19), the translator aimed for conceptual and cultural equivalence of words/phrases. This second forward translation was compared directly with the first and discussed with a psychologist (D.C.). The main discrepancies comprised reliance on overly technical terms. This process resulted in a reconciled U.K. English version, which a second, independent translator (R.L.M.) then back-translated into German. Discrepancies with the revised German DSQOLS were discussed, resolved, and agreed upon between R.L.M., D.C., and the first translator. The few discrepancies identified concerned the meaning of particular phrases and conceptual equivalence.

To ensure content validity, clinicians and a psychologist reviewed the final English version of the questionnaire to assess its relevance, appropriateness, clarity, and comprehensiveness. Cognitive debriefing (a think-aloud technique) was used to pilot this version with four DAFNE participants in Galway, Ireland. They commented on the questionnaire; its layout, comprehensiveness, redundancy, and ease of understanding and completion; length of time taken to complete it; and any additional comments. Feedback, at this stage of piloting, indicated that the questionnaire was comprehensible and acceptable with one exception. Response options for the 57 burden items were amended slightly so that people were asked to rate their agreement with the statements on a 6-point Likert scale labeled “very strongly agree” to “do not agree at all” rather than “perfectly” to “not at all.” This version was discussed with a further four participants from the same center who indicated that questions

Table 1—Sample characteristics and DSQOLS scores

	Database study		Irish study	Psychosocial study*
	EFA	CFA		
Total n	510	511	438	262
Age (years)				
n	509	510	438	262
Mean (SD)	40 (13)	40 (14)	38 (12)	40 (14)
Range	18–73	17–78	18–74	17–73
Sex (% female)	241 (47%)	254 (50%)	233 (53%)	131 (50%)
Duration (years)				
n	503	507	435	262
Mean (SD)	17 (13)	17 (13)	16 (11)	18 (13)
Range	0–65	0–55	1–58	0–55
HbA <sub>1c</sub>				
n	496	480	438	262
Mean (SD)	8.8 (1.6)	8.7 (1.6)	8.3 (1.3)	8.5 (1.5)
Range	4.9–16.6	5.2–14.9	5.0–13.5	5.4–14.2
Presence of complications	193 (38%)	203 (45%)	—	—
DSQOLS: total group**				
Social aspects				
n	970			
Mean (SD)	75.6 (19.2)			
Range	0–100			
Participants at floor	0.1			
Participants at ceiling	2.7			
Fear of hypoglycemia				
n	970			
Mean (SD)	67.0 (23.8)			
Range	0–100			
Participants at floor	0.3			
Participants at ceiling	5.4			
Dietary restrictions				
n	969			
Mean (SD)	65.1 (23.7)			
Range	0–100			
Participants at floor	0.3			
Participants at ceiling	4.7			
Physical complaints				
n	970			
Mean (SD)	68.4 (21.8)			
Range	0–100			
Participants at floor	0.3			
Participants at ceiling	3.7			
Anxiety about the future				
n	970			
Mean (SD)	44.5 (26.5)			
Range	0–100			
Participants at floor	4.2			
Participants at ceiling	2.0			
Daily hassles				
n	972			
Mean (SD)	55.0 (25.0)			
Range	0–100			
Participants at floor	2.1			
Participants at ceiling	3.5			
Total score (burden)				
n	966			

Continued on p. 1120

and response options made sense and language was clear.

### Population

Baseline data were analyzed from three studies within the DAFNE Collaborative. The Database Study collects comprehensive biomedical and psychosocial data from participants at ten centers in the U.K. (20). The Irish study is a cluster-randomized trial evaluating two different methods of follow-up of DAFNE graduates (21). The psychosocial study is a longitudinal evaluation of structured education conducted to identify predictors of QoL and glycemic outcomes. Ethics approvals were obtained from the Trent Research Ethics Committee (REC), National University of Ireland Galway REC, and King's College REC, respectively. Inclusion criteria were similar for each study: adults (aged  $\geq 17$  years) with type 1 diabetes of at least 6-months' duration who had agreed to participate in the DAFNE program. Eligible participants were recruited from 10 hospitals in England for the "database study," 6 hospitals in Ireland for the "Irish study," and 12 hospitals in England and Scotland for the "psychosocial study."

### Study variables

The DSQOLS was completed by all participants in each study prior to receiving DAFNE training along with other psychosocial measures. The ADDQoL (10,22) was completed by a subsample of participants ( $n = 42$ ) in the Irish study at baseline to assess concurrent validity. The ADDQoL provides a composite rating of the average weighted impact (AWI) of diabetes, derived from ratings of 18 potentially applicable domains of life (e.g., "working life," "family life"), indicating the individualized impact of diabetes on the domain (i.e., impact  $-3$  to  $1$ , weighted by importance  $0-3$ ). The AWI score is derived by dividing the sum of the weighted ratings by the number of applicable domains. Scores for single domains and the AWI range from  $-9$  (maximum negative impact of diabetes) to  $9$  (maximum positive impact of diabetes). Two overview items, scored individually, measure "present quality of life" [scores ranging from  $-3$  (extremely bad) to  $3$  (excellent)] and "diabetes-dependent QoL" [scores ranging from  $-3$  (maximum negative impact of diabetes) to  $3$  (maximum positive impact of diabetes)].

The WHO-5 (version 5 of the World Health Organization Well-Being Index)

Table 1—Continued

	Database study		Irish study	Psychosocial study*
	EFA	CFA		
Mean (SD)	66.7 (18.5)			
Range	4.6–100			
Participants at floor	0			
Participants at ceiling	0.1			
DSQOLS PWTSS				
<i>n</i>	986			
Mean (SD)	58.1 (13.8)			
Range	4.0–95.0			
Participants at floor	0			
Participants at ceiling	0			

Data are percent unless otherwise indicated. \*Majority of participants in the psychosocial study are included within the database study. \*\*Descriptives from database study participants (total group).

includes five statements (e.g., “I have felt cheerful and in good spirits”) assessing positively worded depressed mood. Respondents rate their agreement with each item, using a 6-point Likert scale from 0, “none of the time,” to 5, “all of the time,” in relation to the past 2 weeks (23,24). Items are summed to form a total well-being score (ranging from 0 to 25), with higher scores representing greater well-being (or less depressed mood).

A single-item, global measure of life satisfaction was used from the fourth edition of the Personal Well-Being Index for Adults (25). This asks participants to rate their satisfaction with their “life right now” on a 10-point Likert scale from 0, “completely dissatisfied,” to 10, “completely satisfied.”

The latter two measures were completed only by participants in the psychosocial study and were used to assess discriminant validity. For all three studies, demographic and clinical data were collected, including the presence of long-term complications of diabetes (retinopathy, nephropathy, neuropathy, or macrovascular disease or sequelae thereof).

### Analysis

In order to determine the structure of the 57 DSQOLS burden items, the database study sample ( $N = 1,021$ ) was split randomly in two (using SPSS), with one-half of the sample used for exploratory factor analyses (EFAs) ( $n = 510$ ) and one-half used for confirmatory factor analysis (CFA) ( $n = 511$ ). Experts differ in their recommendations for the minimum sample size required for conducting factor analyses. Comfrey and Lee (26) consider a sample size of 300 as good and 500

very good, while Gorsuch (27) makes recommendations based on the ratio of participants to items, stating that a minimum of five participants is required per item. Thus, with 57 items, a minimum sample of 285 is required. In a review of studies that recommended minimum sample sizes for this type of analysis, 400 was the upper limit of the recommendations (28). EFA was carried out using maximum likelihood with Geomin oblique rotation to obtain standardized estimates. Item-component loadings of  $>0.30$  were considered significant based on recommendations for minimum loading of an item (29).

CFA was used to confirm the factor structure of the 57 DSQOLS burden items using the total sample from the database study.  $\chi^2$ , comparative fit index (CFI), a root mean square error of approximation (RMSEA), and standardized root mean square residual (SRMR) were used to evaluate the fit between the model and the data. CFIs of  $\geq 0.90$  indicate a good fit to the data (30). A RMSEA value  $<0.08$  indicates an acceptable fit to the data, while values  $<0.05$  indicate a good fit to the data (30). Well-fitting models obtain SRMR values  $<0.05$ , but values as high as 0.08 are deemed acceptable (31).

Internal consistency reliability was evaluated using Cronbach  $\alpha$  statistics and item-total correlations. As recommended by Bott et al. (12), for facilitation of comparability of the different DSQOLS scores, crude scores were converted to a 100% scale (score – minimum score)  $\times$  100/(maximum score – minimum score). Higher scores on each subscale indicate a better QoL (i.e., less negative impact of diabetes) or greater satisfaction with treatment. For calculation of the

preference-weighted treatment satisfaction score (PWTSS), ratings on each treatment goal are multiplied by the corresponding degree of satisfaction with the achievement of those goals. The sum of those 10 products gives the PWTSS, which is converted to a 100% scale.

Concurrent validity was assessed by correlating (Pearson  $r$ ) DSQOLS subscale scores, including the PWTSS, with each other and (using a subsample of 42 from the Irish study) with scores on another, validated measure of diabetes-specific QoL, the ADDQoL (10). Moderate to strong relationships were expected between the DSQOLS subscales, ADDQoL AWI score, and diabetes-dependent QoL overview item.

Discriminant validity was assessed by correlating (Pearson  $r$ ) the DSQOLS subscales, including the PWTSS, and total score with measures of depressed mood (WHO-5), generic QoL (ADDQoL “present QoL” overview item), and “life satisfaction,” with weak to moderate correlations expected (32).

With data from the database study, known-groups validity was assessed by comparing the scores on the DSQOLS subscales, including the PWTSS, between those with diagnosed diabetes-related complications and those without. It was expected that those with complications would report significantly lower DSQOLS subscales scores, indicating that diabetes impaired their QoL. Statistical analyses were conducted using SPSS, version 17.0, and Mplus 6.1 software.

## RESULTS

### Population characteristics

The demographic and clinical characteristics of each study group were very similar (Table 1). The mean age ranged from 38 to 40 years, with mean diabetes duration ranging from 16 to 18 years and mean baseline HbA<sub>1c</sub> ranging from 8.3 to 8.8%. Complications data are presented only for participants of the Database Study. Of the 911 (89%) participants for whom data were available, 396 (44%) had one or more long-term complications of diabetes.

### DSQOLS structure

For this analysis, data were available for 995 of 1,021 database study participants. Twenty-four had more than one-half of their data missing; hence, the initial EFA was based on  $n = 491$  and the CFA on  $n = 480$ . Of these 971 case subjects, 966 had completed all DSQOLS questions. Five participants had missed one or two

Table 2—Factor loadings for the 57 items relating to daily restrictions and burdens [presented in order of strength of factor loadings, with the highest factor loadings presented in boldface (database study EFA sample)]

Item no. (English version)	Item wording	Social aspects	Fear of hypoglycemia	Dietary restraint	Physical complaints	Anxiety about future	Daily hassles
40	Because of diabetes I cannot pursue my hobbies as I wish	<b>0.752</b>	−0.039	0.032	0.052	0.024	−0.070
51	Because of diabetes it is much harder to make friends	<b>0.703</b>	0.180	0.023	−0.025	−0.209	−0.100
49	Because of diabetes my family life is affected	<b>0.695</b>	−0.042	0.001	0.002	0.101	0.015
34	Because of my diabetes I cannot spend my free time the way I would like	<b>0.680</b>	−0.067	0.146	0.094	0.002	−0.006
28	Because of diabetes I have less contact with friends or acquaintances	<b>0.661</b>	0.022	−0.038	0.132	−0.151	−0.011
35	I feel like a disabled person	<b>0.617</b>	0.020	−0.008	0.220	−0.013	0.035
44	Diabetes constantly causes problems while dealing with other people	<b>0.599</b>	0.170	0.106	0.052	−0.107	−0.140
6	I feel as if I am less attractive to others because of diabetes	<b>0.598</b>	0.012	−0.098	−0.096	0.136	0.132
9	It is a burden for me how other people react to my diabetes	<b>0.589</b>	0.094	−0.052	−0.184	0.032	0.184
4	Because of diabetes my relationship with my partner has become worse	<b>0.561</b>	0.010	−0.010	0.061	0.005	0.022
39	Because of diabetes other people treat me like a “sick person”	<b>0.549</b>	0.072	0.126	−0.030	−0.007	−0.002
26	Diabetes interferes with my future plans	<b>0.467</b>	−0.069	0.088	0.129	0.252	0.033
18	Because of diabetes I feel anxious or threatened	<b>0.458</b>	0.219	−0.084	0.156	0.103	0.063
7	Because of diabetes I feel sad or depressed	<b>0.416</b>	0.019	−0.072	0.127	0.226	0.201
13	Because of diabetes traveling is complicated and troublesome	<b>0.415</b>	0.110	0.106	−0.012	−0.049	0.319
33	I am dissatisfied with the amount of time I have to spend for medical consultations	<b>0.414</b>	−0.033	0.055	0.188	0.063	0.100
20	Other people find it hard to understand my problems with diabetes treatment	<b>0.396</b>	0.011	0.058	0.095	0.073	0.190
15	Diabetes prevents me from spontaneous physical activities	<b>0.360</b>	0.116	0.104	0.175	−0.053	0.146
27	I get an uncomfortable feeling when I think about the dangers of a severe episode of low blood glucose	0.019	<b>0.819</b>	−0.025	−0.015	0.011	−0.025
14	I get anxious and nervous when I think about the dangers of episodes of low blood glucose	−0.056	<b>0.772</b>	−0.054	0.080	0.010	0.182
10	I feel nervous and restless when I think about episodes of low blood sugar	0.062	<b>0.763</b>	−0.128	0.008	−0.027	0.180
57	When I think about the dangers associated with severe episodes of low blood glucose I wonder how often I will remain unharmed	−0.018	<b>0.744</b>	0.052	−0.013	0.123	−0.126
22	I unnecessarily worry too much about episodes of low blood glucose	−0.036	<b>0.739</b>	0.049	0.116	−0.151	0.083
48	I am worried about having a severe episode of low blood glucose at night	−0.096	<b>0.708</b>	−0.041	0.029	0.159	0.056
56	I am worried that I could easily panic in the event of an episode of low blood sugar	0.173	<b>0.667</b>	0.048	−0.045	0.025	−0.120
43	It upsets my stomach when I think about the dangers of severe episodes of low blood glucose	0.130	<b>0.664</b>	0.013	0.089	−0.125	−0.019

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Table 2—Continued

Item no. (English version)	Item wording	Social aspects	Fear of hypoglycemia	Dietary restraint	Physical complaints	Anxiety about future	Daily hassles
36	I am worried that I could sustain physical injury in the event of a severe episode of low blood glucose	0.133	<b>0.597</b>	0.067	0.006	0.057	−0.077
31	I am concerned about getting into embarrassing situations because of episodes of low blood glucose	0.211	<b>0.587</b>	0.023	−0.090	0.068	0.071
52	It bothers me that I have to frequently think about possible causes and mistakes after episodes of low blood glucose	0.131	<b>0.505</b>	0.129	−0.064	0.140	0.067
42	It bothers me that I cannot eat as spontaneously as people who do not have diabetes	0.026	−0.018	<b>0.721</b>	−0.061	0.115	0.123
29	I wish I could eat more the way I want to, without having to plan everything beforehand	0.007	−0.004	<b>0.711</b>	0.017	0.039	0.122
47	I often cannot eat as much as I would like	0.045	−0.005	<b>0.676</b>	0.193	−0.065	−0.016
37	It bothers me that I cannot eat like other people	0.152	0.034	<b>0.670</b>	−0.079	0.028	0.071
55	I would like to eat a greater amount of certain foods which increase my blood glucose strongly	−0.042	0.012	<b>0.669</b>	0.075	0.071	−0.035
24	I cannot eat as much as I want of certain foods	−0.062	−0.002	<b>0.636</b>	0.177	−0.028	−0.043
23	I have to give up good-tasting foods	0.053	0.121	<b>0.514</b>	0.182	−0.097	−0.053
54	It bothers me that I have to inject insulin before I know how much I would really like to eat or I really can eat	0.072	0.113	<b>0.414</b>	0.008	0.170	0.107
21	I feel physically unwell	0.180	−0.003	−0.063	<b>0.728</b>	0.001	0.098
32	I feel weak or lazy	0.045	0.024	0.038	<b>0.689</b>	0.052	0.129
11	I feel tired and exhausted	0.033	0.011	−0.005	<b>0.602</b>	0.062	0.248
19	I suffer from thirst or having a dry mouth	−0.117	0.128	0.036	<b>0.550</b>	0.047	0.096
17	Because of high blood glucose values after a meal I often feel unwell or less efficient	0.052	0.013	−0.044	<b>0.547</b>	0.135	0.145
30	I suffer from frequent infections, itching or skin problems	0.093	0.060	0.029	<b>0.521</b>	0.037	−0.077
25	Because of diabetes I often have physical complaints	0.237	−0.006	0.078	<b>0.516</b>	0.033	−0.058
50	Because of diabetes my physical strength is restricted	0.360	−0.019	0.100	<b>0.480</b>	−0.006	−0.052
3	I suffer from pain because of diabetes	0.180	0.046	−0.017	<b>0.459</b>	0.045	−0.017
16	I suffer from frequent urination	−0.025	0.118	0.113	<b>0.449</b>	−0.028	0.002
38	I am often worried about the long-term complications of diabetes	−0.059	0.206	0.047	0.055	<b>0.731</b>	−0.050
8	I am worried about my future health	0.024	0.013	0.015	0.093	<b>0.722</b>	0.009
5	I am worried that my life could be shorter because of diabetes	0.098	0.044	−0.037	0.037	<b>0.660</b>	0.016
41	I have to frequently think about diabetes and its consequences	0.202	0.069	0.150	−0.034	<b>0.497</b>	0.052
46	I frequently worry that I may become helpless and may need constant care later on	0.161	0.317	0.116	0.098	<b>0.317</b>	−0.042
12	It bothers me that I have to spend so much time on my diabetes treatment	0.311	−0.034	0.188	0.057	0.002	<b>0.552</b>
1	It bothers me that I have to measure my blood glucose so often	−0.019	−0.008	0.261	0.043	−0.023	<b>0.525</b>
2	It is a burden for me that I need to constantly think about my food plan	−0.007	0.054	0.381	0.057	0.002	<b>0.510</b>
53	It bothers me how much diabetes controls my life	0.292	0.033	0.267	0.023	0.214	<b>0.359</b>
45	It bothers me that I have to take my diabetes supplies (e.g., blood testing equipment) with me whatever I do	0.233	0.070	0.253	−0.105	0.095	<b>0.305</b>

questions. Regression imputation was used to impute values.

For determination of the number of factors to extract from the EFA, goodness-of-fit indices, a scree plot of eigenvalues, and the residual correlation matrix were examined. A six-factor solution was indicated and appeared to fit the data well with six interpretable factors [ $\chi^2 = 2,999.2$ ,  $df = 1,269$ ,  $CFI = 0.898$ ,  $RMSEA = 0.053$ , and  $SRMR = 0.031$  (Table 2)]. This reflected the same factor structure as the revised, 57-item, unpublished German version of the DSQOLS and mirrored the factor analysis of the original German 44-item burden scale. Only four items had a loading of  $>0.3$  on a second factor (items 2, 12, 13, and 50), and none had a loading  $>0.4$ . For the unrotated solution, six factors account for 57% of the total variance.

A CFA was run on the second half of the database study data. Model fit was good ( $\chi^2 = 4,182.3$ ,  $df = 1,524$ ,  $P < 0.001$ ,  $CFI = 0.85$ ,  $RMSEA = 0.06$ , and  $SRMR = 0.06$ ) but was improved by allowing nine residuals to covary and by allowing item 41 to cross-load on the social aspects subscale ( $\chi^2 = 3,665.6$ ,  $df = 1,514$ ,  $P < 0.001$ ,  $RMSEA = 0.05$ ,  $CFI = 0.88$ , and  $SRMR = 0.05$ ). Residuals were covaried for items with very similar content and where we can assume that they share specific variance in addition to the common factor variance. Although improving overall model fit, their inclusion had very little effect on the factor loadings. This model was then run on the full database study dataset, where model fit was slightly better ( $\chi^2 = 5,453.2$ ,  $df = 1,514$ ,  $P < 0.001$ ,  $RMSEA = 0.05$ ,  $CFI = 0.88$ , and  $SRMR = 0.05$ ), although eliminating the cross-loading did not make the fit appreciably worse ( $\chi^2 = 5,531.5$ ,  $df = 1,515$ ,  $P < 0.001$ ,  $RMSEA = 0.05$ ,  $CFI = 0.88$ , and  $SRMR = 0.05$ ). This was the preferred model.

The identification of distinct (though highly correlated) DSQOLS subscales does not preclude the existence of a single underlying diabetes-specific QoL scale. A second-order factor analysis, where each of the six factors loaded on a single second-order factor, was conducted. Fit of this model was not appreciably worse than when the factors were allowed freely to intercorrelate ( $\chi^2 = 5,676.1$ ,  $df = 1,524$ ,  $P < 0.001$ ,  $RMSEA = 0.05$ ,  $CFI = 0.88$ , and  $SRMR = 0.05$ ). This provided confirmation of an underlying QoL factor indicated by six distinct subscales. Factor loadings of each subscale on the second-order factor

were high (0.75–0.92). A one-factor model did not fit well ( $\chi^2 = 13,009.1$ ,  $df = 1,539$ ,  $P < 0.001$ ,  $RMSEA = 0.09$ ,  $CFI = 0.66$ , and  $SRMR = 0.07$ ).

#### Internal consistency reliability (database study)

The seven DSQOLS subscales each had excellent internal consistency: social aspects ( $N$  items = 18,  $\alpha = 0.93$ ), fear of hypoglycemia ( $N$  items = 11,  $\alpha = 0.94$ ), dietary restrictions ( $N$  items = 8,  $\alpha = 0.89$ ), physical complaints ( $N$  items = 10,  $\alpha = 0.89$ ), anxiety about the future ( $N$  items = 5,  $\alpha = 0.87$ ), daily hassles ( $N$  items = 5,  $\alpha = 0.85$ ), and Preference-Weighted Treatment Satisfaction Scale ( $N$  items = 20,  $\alpha = 0.74$ ). Item total correlations for each subscale were all  $>0.5$  ( $r = 0.51$ – $0.79$ ). Descriptive statistics for the DSQOLS subscales showed a good distribution of scores and low floor (score of 0) and ceiling (score of 100) effects supporting the reliability of this scale (Table 1).

#### Concurrent validity (database study)

The six DSQOLS burden subscales were significantly intercorrelated ( $r = 0.52$ – $0.72$ ,  $P < 0.001$ ). The DSQOLS subscale scores and the DSQOLS total score were correlated (moderately to strongly) with the ADDQoL AWI score and to a lesser extent (weak to moderately) with the diabetes-dependent ADDQoL overview item (Table 3).

#### Discriminant validity (psychosocial study and Irish study subsample)

As predicted, all the DSQOLS subscales had weak to moderate, positive correlations with depressed mood (WHO-5), generic QoL (ADDQoL overview item), and “life satisfaction,” indicating that

they are measuring different constructs (Table 3).

#### Known groups validity (database study)

Participants with diagnosed diabetes-related complications reported significantly lower (worse) scores on each of the DSQOLS subscales and total score with the exception of the dietary restrictions and daily hassles subscales, which showed no difference (Table 4).

**CONCLUSIONS**—This study aimed to develop a linguistically validated U.K. English translation of the German DSQOLS and to examine its psychometric properties in adults with type 1 diabetes in the U.K. and Ireland. Following forward-backward translation and reconciliation and piloting (with adults with type 1 diabetes and review by clinicians in Ireland), face and content validity of the U.K. English translation were established.

Examination of the scale structure using EFA revealed a six-factor solution, confirmed with two independent CFAs, demonstrating good fit of this model to available datasets. The structure reported here reflects the six-factor structure of the 44-burden items from the original German version. An equivalent factor structure was not expected because of the modifications described earlier. Reliability analyses were satisfactory for each subscale. When a single factor was fitted to the six DSQOLS burden subscales, this model provided a very good fit to the data, supporting the use of a DSQOLS total score.

Moderate to strong correlations were demonstrated between DSQOLS scores as well as between the DSQOLS scores and

**Table 3—Correlations between DSQOLS subscales, ADDQoL, and WHO-5 Well-Being and Life Satisfaction scales (psychosocial study and subsample of Irish study)**

DSQOLS	ADDQoL				
	AWI score	“My present quality of life”	“If I did not have diabetes”	WHO-5 Well-Being	Life Satisfaction
Social aspects	0.78**	0.33*	0.38*	0.46**	0.50**
Fear of hypoglycemia	0.50**	0.20	0.30	0.31**	0.34**
Dietary restrictions	0.50**	0.27	0.47**	0.32**	0.27**
Physical complaints	0.78**	0.39*	0.32	0.54**	0.41**
Anxiety about future	0.66**	0.26	0.35*	0.35**	0.42**
Daily hassles	0.65**	0.38*	0.45**	0.43**	0.39**
Total score	0.82**	0.33	0.40*	0.50**	0.49**

$n = 34$ – $42$  for ADDQoL measures.  $n = 245$ – $252$  for WHO-5 and Life Satisfaction measures. \*\* $P < 0.001$ , \* $P < 0.05$  for ADDQoL measures.



Table 4—Relationship between DSQOLS subscales and presence of complications (database study)

	Complications present		Complications absent		t, df, and P
	n	Mean (SD)	n	Mean (SD)	
Social aspects	379	72.9 (20.2)	484	77.6 (18.4)	t = 3.6, df = 861, P < 0.001
Fear of hypoglycemia	379	64.2 (25.4)	484	68.4 (23.0)	t = 2.5, df = 770, P < 0.05
Dietary restrictions	377	65.1 (23.0)	485	64.8 (24.7)	t = -2.0, df = 832, NS
Physical complaints	379	64.3 (23.4)	484	70.8 (20.3)	t = 4.3, df = 751, P < 0.001
Anxiety about future	378	40.7 (26.3)	485	47.3 (25.9)	t = 3.7, df = 861, P < 0.001
Daily hassles	379	55.6 (25.4)	486	53.9 (24.8)	t = -1.0, df = 862, NS
DSQOLS total score	377	64.3 (19.1)	482	68.1 (18.0)	t = 3.0, df = 857, P < 0.01
Treatment satisfaction (PWTSS)	383	56.9 (13.2)	495	59.3 (14.3)	t = 2.6, df = 850, P < 0.01

the ADDQoL AWI score, suggesting that these are assessing similar underlying constructs providing evidence of concurrent validity. Given the mismatch between the structure of the two scales [i.e., the DSQOLS has six subscales (summarizing its 57 items) and the separate 20-item Preference-Weighted Treatment Satisfaction Scale, and the ADDQoL has one overall score based on the AWI for all 19 domains], the moderate correlations are considered reasonable and the strong correlations highly satisfactory. The weaker correlations between the DSQOLS subscales and the ADDQoL diabetes-dependent overview item were to be expected, as the latter is not considered sufficient to capture the full impact of diabetes on QoL (10).

Better scores on the DSQOLS subscales were associated with greater well-being (less depressed mood), generic QoL, and life satisfaction, but the correlations were sufficiently weak to indicate that various scales measure different constructs. Participants with diagnosed complications of diabetes had significantly worse scores on four of six of the DSQOLS burden subscales, the PWTSS, and DSQOLS total score. This provided support for the ability of this questionnaire tool to discriminate between different groups of respondents.

Sensitivity of the DSQOLS to treatment effects and test-retest reliability has not been demonstrated in this study, although work using the German version has shown that it is sensitive to treatment effects in a comparison of insulin pump and multiple daily injection therapy (33). Work is underway to examine the sensitivity of this instrument for detecting changes in QoL after structured education for adults with type 1 diabetes.

There is a growing need for valid, reliable, and responsive questionnaires to assess outcomes in diabetes research and

clinical practice. Management of type 1 diabetes has evolved from fixed daily insulin doses (as prescribed) to more flexible but complex insulin dose self-adjustment based upon carbohydrate consumption and self-monitoring of blood glucose levels. The evidence presented indicates that DSQOLS is an appropriate tool for evaluating structured education courses that promote flexible intensive insulin therapy. Like the ADDQoL, the DSQOLS captures the impact of diabetes on various aspects of life known to be important for QoL (e.g., family, friendships, and dietary freedom) (10). However, the DSQOLS also enables participants to indicate how they feel about specific aspects of type 1 diabetes management, which are increasingly common among those who have received structured diabetes education, such as carbohydrate counting and flexible insulin dose adjustment. The DQOL questionnaire (11) previously offered this type of approach to diabetes-specific QoL assessment but has become outdated. Unlike existing measures, the DSQOLS also offers the opportunity to assess individual treatment goals as well as preference-weighted treatment satisfaction in a single instrument.

The need for a focus on patient-reported outcomes in addition to biomedical end points is increasingly recognized internationally (1,2,4). The length of the DSQOLS may be considered a limitation; we believe this is offset by the unique contributions of its subscales, each capturing important aspects of diabetes-specific QoL and reducing the need for multiple questionnaires to achieve a holistic assessment. Although its length was not criticized by participants in our studies, a shorter version of the DSQOLS might be more acceptable to respondents and, hence, promote its wider use in clinical and research environments. Validation

of a shorter version of this measure is under development.

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