

## Assessing Quality of Life for New Diabetes Treatments and Technologies: A Simple Patient-Centered Score

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### Abstract

#### **Background:**

A simple quality of life measure is needed for use in diabetes, particularly for the assessment of new treatments and technologies. We devised and validated a patient-centered quality of life (PCQoL) measure that should be applicable to routine clinical practice or trial of therapies.

#### **Methods:**

People with diabetes completed a two-part, PCQoL questionnaire where they nominated five aspects of general- and diabetes-related life judged most important for their overall quality of life and rated each for current level of satisfaction. Scores derived from the questionnaire were compared with a reference measure—the Diabetes Control and Complications Trial diabetes quality of life (DQoL) score. Both were repeated after 1 month. The participants were 72 diabetic patients (60% with type 1 diabetes); 29 people with type 1 diabetes were treated by continuous subcutaneous insulin infusion (CSII) and 14 were treated by multiple daily insulin injections (MDI).

#### **Results:**

Patients most often cited family and relationships or fear of complications and hypoglycemia as important facets of quality of life for them. The PCQoL measure was highly correlated with the reference DQoL measure ( $r = 0.73$ ,  $p < 0.0001$ ), had high repeatability ( $r = 0.91$ ,  $p < 0.0001$ ), and could be completed in less than 5 minutes. The test was sensitive enough to detect a better quality of life in CSII-treated patients vs MDI-treated patients.

#### **Conclusion:**

The PCQoL measure is simple, quick, valid, and suitable for routine use in diabetes or trials of new treatments.

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**Abbreviations:** (CSII) continuous subcutaneous insulin infusion, (DQoL) diabetes quality of life score, (HbA1c) glycated hemoglobin, (MDI) multiple daily insulin injections, (PCQoL) patient-centered quality of life score

**Keywords:** continuous subcutaneous insulin infusion, diabetes mellitus, patient centered, quality of life

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## Introduction

Assessment of quality of life in people with diabetes is increasingly seen as an important aspect of care,<sup>1</sup> particularly as new treatments and services are introduced or investigated that may be more demanding on the one hand but offer improved metabolic control on the other, e.g., multiple daily insulin injections (MDI) and frequent blood glucose monitoring,<sup>2</sup> continuous subcutaneous insulin infusion (CSII, insulin pump therapy),<sup>3</sup> and structured patient education.<sup>4</sup>

Numerous instruments have been used for assessing quality of life in diabetes,<sup>1</sup> which can be broadly classified as generic and applicable to all health conditions (e.g., the Medical Outcomes Study Short-Form General Health Survey, SF-365) or diabetes specific, e.g., the diabetes quality of life (DQoL) score, a measure developed for the Diabetes Control and Complications Trial.<sup>2,6</sup> In almost all cases, assessment is made with these instruments of predetermined domains that the health-care professional considers important for quality of life—pain or mood, for example, in generic indices, or hypoglycemia, injections, and tissue complications in the case of diabetes-related measures. Many of the measures are moderately time-consuming and complicated and are unsuitable for routine clinical practice: the currently most widely used measure, the DQoL, consists of 46 items<sup>6</sup> in a popular version.

However, items or domains in questionnaires predetermined by the health-care professional may not coincide with what the patient considers crucial to their quality of life,<sup>7</sup> e.g., the patient perhaps rating a happy family life far more than feeling unwell from diabetes or its complications. This may partly explain why promising new treatments such as insulin pump therapy, which improve glycemic control, reduce hypoglycemia,<sup>3</sup> and might be expected to improve quality of life, have been shown to do so in some trials<sup>8</sup> but not in others.<sup>9</sup>

More patient-centered (sometimes also called “individual”) measures, such as the Schedule for the Evaluation of Individual Quality of Life, are a response to these limitations<sup>10</sup> and ask patients during an interview to nominate a small number of facets of life that they judge to be important to their overall quality of life and then to rate their current status of each. This approach has received surprisingly little attention in patients with diabetes.

In the present study, we validated a simple self-administered patient-centered quality of life (PCQoL) measure that is

based on general- and diabetes-related life by comparing it to the established DQoL score. We show that a reliable and quick measure such as this might be applicable in routine practice and for assessment of new technology.

## Subjects and Methods

### *Patients and Protocol*

People with type 1 and 2 diabetes were recruited at random from a diabetic clinic; 76 of the 89 patients approached agreed to participate, and complete forms suitable for analysis were received from 72 (60% with type 1 diabetes). The mean (SD) age of the patients was 48.9 (15.0) and the median (range) diabetes duration was 15.5 (0.1–51 years). The ethnic mix of the subjects was 85% Caucasian, 7% African/Afro-Caribbean, 7% Asian from the Indian subcontinent, and 1% Oriental.

Each subject completed two quality of life questionnaires on two occasions 1 month apart, either at the time of their clinic visit or at home 1 month later with return of the form by post. Glycated hemoglobin (HbA1c) was measured by affinity chromatography (Primus Corporation, Kansas City, MO; reference range 4.2–6.2%) at the time of the first questionnaire. Social class was assessed by the National Statistics Socio-Economic Classification,<sup>11</sup> an occupation-based scale used by the United Kingdom Registrar General. Distributions across social class were classes 1 and 2 (managerial and professional: 37.5%), 3 and 4 (intermediate occupations, small employers, and own account workers: 25%), 5 and 6 (craft-related and semiroutine occupations: 16.7%), and 7 and 8 (routine occupations and long-term unemployed: 20.8%).

For sensitivity analysis, we selected a subgroup of 29 people with type 1 diabetes [age 41.8 (12.3) years, diabetes duration 20 (4–25) years, 45% male] treated by CSII and compared them with 14 people with diabetes of similar age [44.2 (13.5) years], diabetes duration [28.5 (6–51) years], and sex (43% male) poorly controlled on MDI and awaiting assessment for insulin pump therapy. Quality of life questionnaires were completed by both groups.

### *Quality of Life Measurement*

The reference measure was the DQoL score,<sup>6</sup> which uses a total of 46 prechosen core items in four primary scales devoted to satisfaction, impact, diabetes worry, and social/vocational worry, with five-point responses from very satisfied (5) to very dissatisfied (1).

The test measure was a patient-centered quality of life score administered in two parts: general- and diabetes-related life. The questionnaire for general life is shown in **Figure 1** (additional clues as outlined in **Table 1** were also added). In each part, subjects nominated five facets of life, in order of importance, judged to be important to them for quality of life (most important rated 5). Clues were given on the questionnaire as suggested examples (**Table 2**). Each aspect was then weighted by the patient for their current level of satisfaction on a five-point Likert scale (5, completely satisfied; 1, not at all satisfied), and a total score was calculated as the products of each facet weighting and its satisfaction rating. Thus, rating family as most important (5) and its level of satisfaction as 3 would score  $5 \times 3 = 15$ . This was added to the second most important facet (4) and its level of satisfaction, say 4 (score  $4 \times 4 = 16$ ), and so on for the five facets. The total was expressed as a percentage of the maximum for the general and diabetes life forms combined and for each separately.

**Table 1.**  
Clues Given to Subjects on Patient-Centered Quality of Life Questionnaire

General life	Family, friends, religion, finances/money, physical health, work/career, hobbies, social/leisure activities, relationships, holidays, feeling happy or content, sex, and exercise
Diabetes-related life	Whether I will get complications (eye or kidney disease), the time it takes to manage my diabetes, flexibility in what I can eat, feeling well in myself, how often I have a low blood sugar level (hypoglycemia), flexibility in how I can exercise without upsetting my diabetes, not having symptoms of high blood sugar (thirst, passing a lot of urine), how much my diabetes affects my family and friends, how much my diabetes interferes with my work/school life, how much my diabetes interferes with my leisure and social life, and how much my diabetes affects my sex life

### Statistical Analysis

We assessed the validity of the patient-centered score by correlating it with DQoL scores using Pearson's method and its reproducibility (and that of the DQoL score) by the correlation of the test-retest scores at 1 month's separation. We investigated age, diabetes duration, and HbA1c as correlates of the patient-centered score using either Pearson's or Spearman's test. Means were compared with Student's *t* test, Mann-Whitney test, or analysis of variance, as appropriate. We also calculated floor (percentage at minimum score) and ceiling (percentage at maximum score) effects, and the internal consistency of the patient-centered score was assessed by calculating Cronbach's  $\alpha$ .

### Results

**Table 2** shows the most frequently cited facets of general and diabetes-related life that people with diabetes judged to be important to them for their overall quality of life. Family and relationships were considered most important in general life and complications and hypoglycemia in diabetes-related life. In both subparts of the questionnaire, patients usually judged physical health or feeling well to be of lesser importance. On the basis of the patients' weighting of these facets (i.e., how well they currently had achieved satisfaction for each item) a PCQoL score was calculated. The time to complete the questionnaire was less than 5 minutes.

### Validity and Repeatability of Patient-Centered Quality of Life Score

**Figure 2** shows that a strong correlation exists between the PCQoL total score (general life plus diabetes-related factors) and the reference DQoL score ( $r = 0.73$ ,  $p < 0.0001$ ).

1. Please list below the 5 aspects of your general life which are most important to you for your overall 'quality of life,' putting them in order of importance. At the bottom of the page are some possibilities, but you may choose something which is not on the list if you think it is important to you.

2. For each choice you list, try to assess how satisfied you are with this aspect of your life at the moment.

Aspects of my life most important to me:

Not at all Satisfied				Completely satisfied
1 _____ 1	2	3	4	5
2 _____ 1	2	3	4	5
3 _____ 1	2	3	4	5
4 _____ 1	2	3	4	5
5 _____ 1	2	3	4	5

Some possible choices (you may choose others if you wish)

Family	Social/leisure activities
Friends	Relationships
Religion	Holidays
Finances/money	Feeling happy or content

**Figure 1.** Patient-centered quality of life questionnaire—General life

**Table 2.**  
Frequency of Citing Various Items as Important in Overall Quality of Life

Facet	Frequency of citation (%)
<b>General Life</b>	
Family	37
Relationships	22
Feeling happy/content	9
Friends	7
Physical health	7
Other	18
<b>Diabetes-related life</b>	
Worry about developing complications	30
Frequency of hypoglycemic episodes	24
Flexibility of diet	14
How much diabetes affects family/friends	8
Feeling well	6
Other	18

Each part of the patient-centered measure was also correlated with the DQoL score:  $r = 0.63, p < 0.001$  (vs general life score) and  $r = 0.68, p < 0.001$  (vs diabetes-related life). The PCQoL measure suggested that, on average, the subjects considered that their general quality of general life was achieved more satisfactorily than their diabetes-related quality of life: mean (95% confidence interval) 66 (61, 71) vs 56 (51, 61),  $p < 0.01$ .

The test-retest repeatability over a 1-month period was good for both the PCQoL score ( $r = 0.91, p < 0.0001$ ) and the reference DQoL score ( $r = 0.90, p < 0.0001$ ). Subscales

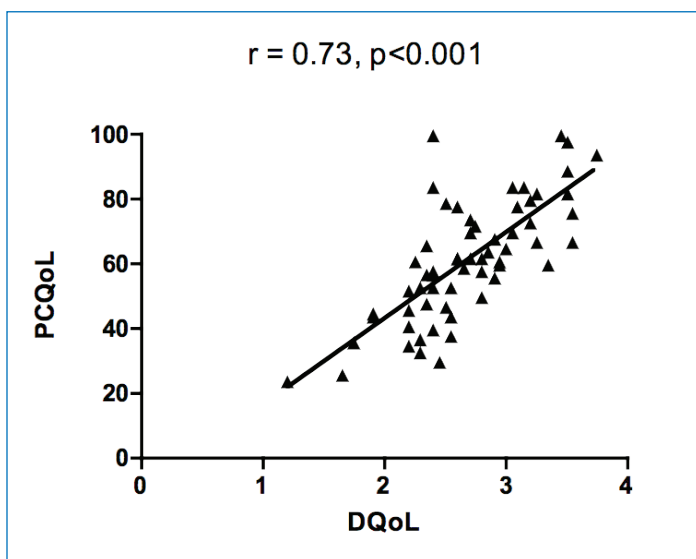
of the patient-centered test also had good repeatability ( $r = 0.87, p < 0.001$  for general life and  $r = 0.89, p < 0.001$  for diabetes-related life). There was a low ceiling effect of 2.8% (i.e., percentage who scored the maximum and could thus not improve further) and no floor effect (i.e., percentage who scored the minimum and could thus not worsen further was zero). Cronbach's  $\alpha$  for internal consistency was satisfactory at 0.80.

**Sensitivity of Patient-Centered Score: MDI vs CSII**

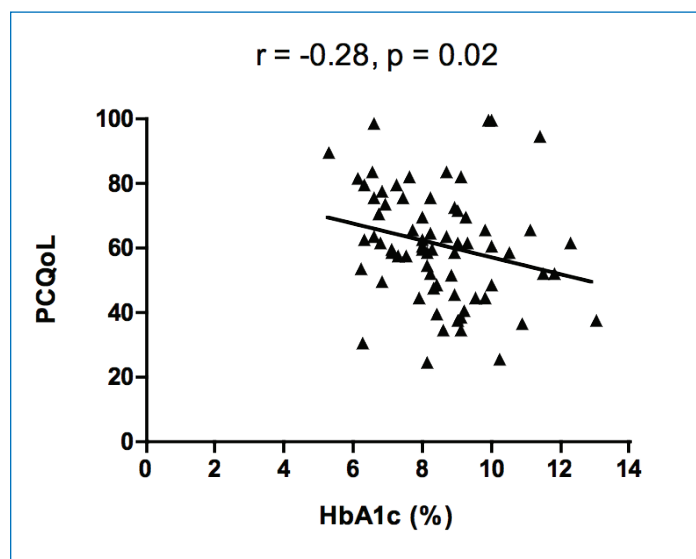
In order to test whether the PCQoL score had sufficient sensitivity to discriminate between groups that might be expected to have a different quality of life, we measured quality of life in two groups of type 1 diabetic subjects matched for age, sex, and diabetes duration but differing in treatment: group 1 was treated by MDI and but failed to achieve good glycemic control and group 2 was treated by CSII. The insulin pump-treated group had significantly better glycemic control than the injection-treated patients [mean HbA1c 7.4 (7.0, 7.8) vs 9.0 (8.1, 9.9),  $p < 0.001$ ] and both quality of life scores were better for pump than for injection-treated subjects [mean PCQoL: 68 (64,73) vs 55.1 (51, 60),  $p < 0.05$ ; mean DQoL: 2.9 (2.8, 3.0) vs 2.4 (2.3, 2.6),  $p < 0.05$ , pump vs injections].

**Correlates of Quality of Life**

There was a significant but relatively weak negative correlation between PCQoL and glycemic control, as measured by HbA1c (Fig. 3;  $r = -0.28, p = 0.02$ ). Age and duration of diabetes were not correlated with quality of life, and the mean score did not differ between men and women or among social classes.



**Figure 2.** Correlation of the PCQoL measure and the reference DQoL score.



**Figure 3.** Correlation of PCQoL score and glycemic control in diabetic patients, as measured by HbA1c.

## Discussion

This study shows that patient-centered quality of life measurement is quick, simple, repeatable, sensitive, and valid in type 1 and type 2 diabetes. It should therefore be suitable for application in routine clinical practice and for assessment of new technologies.

Although clues are offered as possible choices, the score does not depend on exactly which facets of life the subjects consider to be important, only how well patients judge that satisfaction is currently achieved in each of them. The merit of the score is that individuals are allowed to express their unique perception of what is important, and this is thus likely to be independent of patient characteristics such as social class, cultural group, and education. It is of note that physical health and well-being were consistently rated much lower than family and relationships in the general life questionnaire and that feeling well was much lower than fear of complications and hypoglycemia in the diabetes-related questionnaire.

Individual quality of life has received little attention in diabetes to date. Walker and Bradley<sup>12</sup> tested an individualized general quality of life measure (with an imposed diabetes domain) performed by interview in 15 adolescents with type 1 diabetes, but it was poorly related to a reference 52-item DQoL measure for youths. Wagner and colleagues<sup>13</sup> studied individual quality of life domains in 8 children with diabetes but did not measure validity. As with the present research, family and friends were nominated most frequently.

The purpose of our research was not to test whether quality of life in type 1 diabetes is improved on switching from injection to insulin pump therapy, although we found that on a cross-sectional basis that the sensitivity of the PCQoL measure was sufficient to show that quality of life was better in pump-treated subjects than a comparable group of injection-treated subjects. There is debate about what difference in quality of life is clinically meaningful, but, based on a systematic review, a change of 0.5 standard deviation or more with most measures is thought to be detectable by the patient and thus clinically important.<sup>14</sup> With a difference between pump- and MDI-related quality of life of about twice this amount, we suggest that the PCQoL measure would therefore be suitable for use in future randomized controlled trials testing quality of life in diabetic patients allocated to new treatments and management strategies. There is an urgent need for convenient quality of life assessment under these circumstances, research that has been relatively

neglected until recently. A recently described insulin delivery system rating questionnaire for assessment of quality of life in patients using insulin delivery devices and employing seven multi-item subscales also recorded a significantly better score during insulin pump therapy than during injection treatment.<sup>15</sup>

In our study, we also found that there was a significant correlation between quality of life and glycemic control, as assessed by HbA1c. Such a relationship has been noted before with other diabetes-specific quality of life measures, such as the DQoL score,<sup>1,16</sup> but the correlation is often not seen with generic measures.<sup>1</sup> Overall, such findings support the notion that the benefits of good control on tissue complications<sup>2</sup> are not offset by the additional burden and interference to everyday living that intensified regimens may possibly involve.

Because the validity of the PCQoL measure was established here using diabetic subjects who differed in type of diabetes, age, diabetes duration, sex, and social class, the results should be generally applicable and useful in most practices. However, we caution and recognize that a limitation of our study was that we did not study children or very old patients with diabetes, a large group of patients from ethnic minorities, or those with severe disability such as the blind. Such groups will need special study and may nominate different facets of life as important, although since these will be rated in the same way, the resultant measure will likely be valid.

Our study was concerned only with methodology development and validation and was not designed to explore such important issues as the relationship between quality of life and type of treatment in type 2 diabetes (say, insulin delivered by different routes or devices) or the presence and severity of tissue complications. Further well-designed studies should investigate these questions.

We conclude that this simple, quick, patient-centered measure is suitable for application in diabetes management on a routine basis and also should be useful for assessing new technologies.

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