Development and Validation of the Diabetes Quality of Life Brief Clinical Inventory

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Abstract

Objective. To design and test the reliability and validity of a brief, treatment-focused version of the Diabetes Quality of Life (DQOL) questionnaire for use with both type 1 and type 2 diabetes.

Research design and methods. Questionnaire packets including the DQOL, measures of current diabetes self-care behaviors, and demographic and health characteristics were mailed to 1,080 adults with type 1 or type 2 diabetes. A total of 498 patients returned completed packets. A three-stage statistical process was used to understand the underlying structure of the DQOL and to identify items most predictive of self-care behaviors and satisfaction with diabetes control.

Results. Principal components analysis, conducted on 26 items predictive of the main criteria, identified five key underlying factors. For each component, best subset regression analysis was conducted to identify nonredundant questions that best explained self-care behaviors and satisfaction with diabetes control.

A combined set of 15 questions was reliable (alpha = 0.85) and valid, though several questions were more relevant to type 1 or type 2 diabetes. For patients with type 1 diabetes, the 15-item brief inventory was equally or more effective at predicting self-care behaviors (shortened scale $R^2 = 0.360$; full scale $R^2 = 0.254$) and satisfaction with diabetes control (shortened scale $R^2 = 0.562$; full scale $R^2 = 0.580$) than the original 60-item DQOL. For type 2 diabetic patients, only satisfaction with diabetes control was well-predicted, but the 15-item inventory accounted for as much variance as the original 60-item DQOL (shortened scale $R^2 = 0.513$; full scale $R^2 = 0.492$).

Conclusions. The 15-item DQOL Brief Clinical Inventory provides a total health–related quality of life score that predicts self-reported diabetes care behaviors and satisfaction with diabetes control as effectively as the full version of the instrument. In addition, it provides a vehicle for quickly screening patients for readiness and specific treatment-related concerns. It takes about 10 minutes to administer and can be used to identify quality of life issues that might not arise during the typical patient-provider encounter.

INTRODUCTION

The past few decades have witnessed considerable research about health-related quality of life (HRQOL), leading to the development and refinement of a number of generic and disease-specific HRQOL measures. A patient’s quality of life—total physical, mental, and social well-being—has come to be viewed as a critical outcome of disease treatment and control. Consequently, generic and disease-specific HRQOL measures have been used extensively in clinical trials and research initiatives to assess the impact of medical interventions.

A finding underscoring the importance of HRQOL is that clinical variables alone do not comprehensively capture patients’ perceptions of their health. In fact, studies show relatively low correlations between clinical measures of disease activity (e.g., peak flow rates for asthma and hemoglobin A1c [A1C] results for diabetes) and patients’
perceptions of health and well-being. Such low correlations have been reported in several chronic diseases including diabetes, asthma, and chronic obstructive pulmonary disease.

The issue of HRQOL is particularly important for diseases such as diabetes, for which the health care regimen requires ongoing self-care behaviors that can interfere with patients’ desired lifestyles. Providing optimal diabetes care involves recognizing the inherent cost-benefit trade-off between the disease and treatment burden. The Diabetes Control and Complications Trial (DCCT) hinted at this delicate balance by finding that intensive insulin therapy yielded a significant reduction in diabetic complications compared to traditional insulin therapy, but did not lead to improved quality of life. Other research has yielded inconsistent relationships between therapy intensity and quality of life, in part because of the fact that HRQOL is influenced by a myriad of other factors, such as the existence of other health problems, social relationships, marital status, patient knowledge, treatment satisfaction, and perceived ability to control one’s disease.

For health care professionals, a key goal in treating diabetes is to help patients improve their quality of life by identifying and addressing diabetes-related issues. Past research has found, however, that as much as 54% of patient concerns and 45% of patient concerns are neither elicited by providers nor disclosed by patients during a typical office visit. Along these same lines, patients often express dissatisfaction with the information provided to them by their providers and this patient-provider communication is linked to patient compliance with therapy and satisfaction with care. Findings also suggest that improving patient-provider communication benefits patient health and promotes provider loyalty as a consequence of perceived satisfaction with care.

The objective of this study was to develop a valid and reliable, but brief, diabetes-specific HRQOL instrument for use in routine office visits, with specific actionable items to improve provider-patient communication, treatment compliance, and health care satisfaction. Recent short-form quality of life (QOL) measures, such as the Medical Outcomes Study SF-36, short hypertension-specific QOL form, short coronary artery disease-specific QOL form, and short mental-health SF-36, have been successfully developed, in which the goal was to preserve the full item content range, scale structure, reliability, validity, and responsiveness of the original instruments.

Outcome-predictive QOL inventories have been successfully implemented with other specific health problems, such as hypertension, arthritis, and mental health. Our goal, and consequently our analytical approach, differed somewhat from this. We focused on selecting items that differentiate patients in terms of treatment satisfaction and compliance. Items most predictive of these two criteria were retained to build a clinical inventory that highlights clinically significant patient problems.

RESEARCH DESIGN AND METHODS

Overview
First, we reviewed the literature for diabetes-specific QOL measures, and these instruments were reviewed for comprehensiveness and psychometric properties. Based on this review, we selected the Diabetes Quality of Life (DQOL) questionnaire to be our foundation instrument. Second, a panel of experts in diabetes care reviewed the DQOL for comprehensiveness. Third, we administered this instrument, along with a measure of current health care behaviors and demographic characteristics, to 1,080 adults with type 1 or type 2 diabetes. Fourth, we analyzed this data to identify those survey items that best predict regimen adherence and satisfaction with the diabetes regimen. These items became the core of the shortened DQOL instrument. Finally, we conducted analysis to evaluate the statistical performance of this shortened instrument.

Selection of the DQOL
Current HRQOL instruments tend to be lengthy and often lack applicability to both type 1 and type 2 diabetic patients, making them difficult to integrate into routine clinical practice. For example, the Diabetes Care Profile and the Diabetes Treatment Satisfaction Questionnaire are applicable to type 2 diabetes only, whereas the Diabetes-Specific Quality-of-Life Scale is only validated for type 1 diabetes. The Diabetes Quality of Life Clinical Trial Questionnaire and Diabetes-QOL were developed specifically for clinical trials in diabetes.

More recently, an individualized measure, the Audit of Diabetes-Dependent QOL, has been designed wherein respondents rate only personally applicable life domains. This measure is applicable to both type 1 and type 2 diabetes, it lacks generalizability due to its individualized nature. Other instruments, such as the 15-D Health Related Quality of Life measure, were developed abroad and have not been validated for use with American patients.

The DQOL questionnaire, developed for both type 1 and type 2 diabetes as part of the DCCT, was identified through our review as having qualities most amenable to aiding provider-patient communication about treatment. Despite desirable content focus, reliability, and validity, the DQOL in its full form is too lengthy to be completed as part of a provider’s routine office visit. Its 46 core items measure four domains highly relevant to treatment perceptions: satisfaction with treatment, impact of treatment, worry about the future effects of diabetes, and worry about social/vocational issues.

Procedure
We identified 1,080 potential participants from a registry of people receiving health care for type 1 or type 2 diabetes at a large midwestern academic medical center. A packet containing an invitation letter (from the chief diabetes physician), questionnaire, and stamped return envelope was mailed to each potential participant’s home. Reminder letters were mailed to nonresponders 2 weeks later, and follow-up phone calls were made after 3 weeks to encourage participation. Of the 1,080 potential participants, 498 returned their survey packets for a total participation rate of 48%.

Instruments

DQOL instrument
The original DQOL is a 60-item instrument to assess the diabetes-related QOL of participants. Of these items, 13 are limited to children and adolescents with diabetes. The instru-
ment provides an overall scale score, as well as four subscale scores for 1) satisfaction with treatment, 2) impact of treatment, 3) worry about the future effects of diabetes, and 4) worry about social/vocational issues.

Items are scored on a 5-point Likert scale and are of two general formats. One format asks about the frequency of negative impact of diabetes itself or of the diabetes treatment (i.e., “How often do you worry about whether you will pass out?”) and provides response options from 1 (never) to 5 (all the time). The second format asks about satisfaction with treatment and quality of life (i.e., “How satisfied are you with the time you spend exercising?”) and is scored from 1 (very satisfied) to 5 (very dissatisfied). Higher scores on DQOL items and subscales are, therefore, negatively valenced, indicating problem frequency or dissatisfaction. The instrument has been shown to have excellent internal consistency ($r = 0.78–0.92$), test-retest reliability ($r = 0.78–0.92$), and convergent validity for all four subscales for people with type 1 and type 2 diabetes.$^{18,27,52}$

**Statistical Analyses**

The DQOL responses were analyzed in three stages to reduce the number of items while maximizing prediction of the criteria. In the first stage, we assessed the comparability of our data to the original DQOL validation study$^{52}$ by comparing means, standard deviations, variances, and coefficient alphas for the four original DQOL scales. In the second stage, we conducted an initial item analysis in which frequency distributions and the Pearson product-moment correlation with the two criteria were calculated for each of the 46 original adult DQOL items. Items which had a Pearson correlation of at least 0.25, were statistically significant and considered clinically relevant. Twenty-six items met this criteria and were retained for stage 3 analyses.

In the third stage, we identified optimal subsets of items for type 1 and type 2 diabetes. First, we performed principal components analysis on the 26 predictive items for the entire participant sample. Several orthogonal rotations were examined, with varimax rotation yielding the clearest separation of factor loadings. We then used multiple linear regression to model 1) diabetes control satisfaction and 2) reported self-care as a function of the groups of items from the five DQOL components.

Models were built separately in a two-step process for type 1 and type 2 diabetes. In the first step, we used stepwise selection to identify items from each orthogonal principal component that explained significant variance in either diabetes control satisfaction or reported self-care. In the second step, we used best 1–10 variable subset methods with the joint set of items identified in the first step to identify items that jointly and most parsimoniously (based on Schwarz’s BIC and Mallow’s C) explained the maximum amount of variance in diabetes control satisfaction and reported self-care. The two-step approach allowed us to reduce redundancy among items that were highly correlated with each other before trying to explain maximal combined variance from all unique sources of variation in the instrument.

**RESULTS**

**Sample Characteristics**

Of the 498 respondents, 32% had type 1 diabetes, and 68% had type 2 diabetes. Length of time since diagnosis ranged from 1 to more than 20 years, with a median length of time of 8 years. Slightly more than half the respondents were female (53%), and ages for respondents ranged from 21 to more than 80 years, with a median of 51 years. Educational levels ranged from a completed doctoral to less than a high school degree, with 41% having completed just a high school degree. Annual household income ranged from less than $15,000 to more than $100,000, with a median of $37,500. In examining respondents’ health status, subjects reported a number of health problems including hypertension (51%), high cholesterol (45.3%), arthritis (42.4%), sleeping problems (44.6%), and depression (33.3%).

**Comparison of Data With DQOL Validation Sample**

Stage 1 of the analysis directly compared our results to those of the original validation study$^{52}$ to assess whether there were differences in the HRQOL issues faced by these two samples. Our sample reported lower overall diabetes-related quality of life, but worried less about social/vocational issues than did the validation sample. The mean DQOL total score of 2.6 ($SD = 0.7$) for males in this sample was significantly higher (indicating lower QOL) than the mean score of 2.0 ($SD = 0.4$) for the previous sample, ($t = 7.336, P < 0.0001$). Similarly, the mean DQOL total score for women of 2.7 ($SD = 0.8$) was significantly higher (indicating lower QOL) than the previous sample mean score of 2.1 ($SD = 0.4$) ($t = 5.336, P < 0.0001$). No differences between the two samples were observed for worry about diabetes-related events, or for females for diabetes impact.
DQOL reliability coefficients in our sample were comparable to the valida-
tion study, ranging from 0.61 for the Diabetes Worry subscale to 0.94 for
the total DQOL scale score. Detailed examination of missing values indicat-
ed few problems with only two items (Impact Q25 [9%] and Impact Q21
[10%]) having missing value rates as high as 10%. Further, there were no
items for which more than 90% of respondents selected the lowest
response option, which would have suggested that the item did not pose a
quality of life issue for our sample.

**Item Selection**
In Stage 2, we identified 26 items pre-
dictive of self-care and satisfaction
with diabetes control. In stage 3, we
used principal components analysis to
identify groups of items with over-
lapping content. This step yielded five
principal components that accounted
for 9.23–15.35% of the total item variance each and 56.73%
the total item variance collectively. The solution, shown in Table 1,
demonstrated clean separation of components, with only three items
demonstrating minor cross-loadings, and only one item failing to load with
a correlation of at least 0.40 onto any component.

**Type 1 diabetes**
Six items were identified by the two-
stage regression analysis as predictors
of satisfaction with diabetes control ($P < 0.0001$). These items included satis-
faction with the time spent managing diabetes, satisfaction with current
treatment, satisfaction with sex life, satisfaction with burden on family, satis-
faction with exercise, frequency of pain with treatment, frequency of feel-
ing ill, frequency of breaking diet to avoid telling others about diabetes,
frequency of career limitation, and frequency of worry over passing out.

Regression analyses were next con-
ducted to evaluate how well the six-
and nine-item models predicted satis-
faction and self-care, compared to
models containing all 60 DQOL
items. In predicting satisfaction with
treatment, the six-item model had an adjusted $R^2$ of 0.562, compared to
0.580 for the 60-item model. In pre-
dicting self-care behaviors, the six-
item model had an adjusted $R^2$ of
0.360, compared to 0.254 for the 60-
item model. These results suggest that
six- and nine-item solutions are effec-
tively able to predict overall satisfac-
tion with diabetes control and overall
self-care behaviors as well as the full
60-item survey among patients with
type 1 diabetes.

**Type 2 diabetes**
The results differed for type 2 dia-
betes. Six items were identified as pre-
dictors of satisfaction with diabetes
control ($P < 0.0001$). These items
would have...
included satisfaction with the time spent managing diabetes, satisfaction with current treatment, satisfaction with exercise time, frequency of pain with treatment, and frequency of worry over passing out. Similarly, six items were identified as predictors of self-care adherence ($P = 0.0075$). These items included satisfaction with glucose maintenance, satisfaction with diabetes knowledge, satisfaction with exercise time, frequency of breaking diet to avoid telling others about diabetes, frequency of worry over missing work, and frequency of worry over passing out.

Regression analyses evaluated how well these six-item models predicted satisfaction and self-care, as compared to models that contained all 60 DQOL items. In predicting satisfaction with treatment, the six-item model had an adjusted $R^2$ of 0.513, compared to 0.492 for the 60-item model. In predicting self-care behaviors, the six-item model had an adjusted $R^2$ of 0.117, compared to 0.196 for the 60-item model. These results suggest that, for type 2 diabetes, overall satisfaction with diabetes control was predicted as well by the six-item survey as by the 60-item survey, though overall self-care behaviors were predicted slightly better by the overall 60-item model than by the six-item reduced model.

### Constructing the DQOL Short-Form Clinical Inventory

These four sets of items (two each from type 1 and type 2 diabetes analyses) were then combined into a master 15-item set (several items were significant in more than one of the previous regression models). A total scale score was calculated for this shortened scale based on regression weights. The new inventory showed good internal consistency ($\alpha = 0.85$).

The new total score was correlated with the full DQOL scale and with the individual DQOL subscales. The uncorrected correlation between the two total scales was 0.81, and correlation corrected for attenuation due to the instrument’s reliability was 0.91, suggesting that the shortened version was able to explain the vast majority of variation in total DQOL scores.

Equivalent analysis suggested that the shortened scale correlated strongly with each of the individual subscales from the full instrument. The strongest relationship was with the satisfaction subscale (uncorrected $r = 0.84$ and

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<table>
<thead>
<tr>
<th>Table 2. Regression Parameters for Regression Models</th>
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<tbody>
<tr>
<td><strong>Items included in model of satisfaction with diabetes control (type 1)</strong></td>
</tr>
<tr>
<td>Satisfaction with time managing diabetes &amp; 0.387 &amp; 4.83 &amp; &lt; 0.0001</td>
</tr>
<tr>
<td>Satisfaction with current treatment &amp; 0.426 &amp; 5.59 &amp; &lt; 0.0001</td>
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<tr>
<td>Satisfaction with sex life &amp; -0.046 &amp; -0.61 &amp; 0.5438</td>
</tr>
<tr>
<td>How often subject has a bad night’s sleep &amp; 0.114 &amp; 1.55 &amp; 0.1245</td>
</tr>
<tr>
<td>How often feels diabetes limits career &amp; 0.128 &amp; 1.59 &amp; 0.1123</td>
</tr>
<tr>
<td>How often subject worries about missing work &amp; -0.189 &amp; -2.53 &amp; 0.0127</td>
</tr>
<tr>
<td><strong>Items included in model of reported adherence with self-care regimen (type 1)</strong></td>
</tr>
<tr>
<td>Satisfaction with glucose maintenance time &amp; -0.216 &amp; -2.67 &amp; 0.0087</td>
</tr>
<tr>
<td>Satisfaction with current treatment &amp; -0.157 &amp; -1.78 &amp; 0.0772</td>
</tr>
<tr>
<td>Satisfaction with burden on family &amp; 0.179 &amp; 2.05 &amp; 0.0430</td>
</tr>
<tr>
<td>Satisfaction with exercise time &amp; -0.332 &amp; -4.48 &amp; &lt; 0.0001</td>
</tr>
<tr>
<td>How often has pain with treatment &amp; -0.217 &amp; -2.47 &amp; 0.0150</td>
</tr>
<tr>
<td>How often feels physically ill &amp; 0.175 &amp; 1.84 &amp; 0.0691</td>
</tr>
<tr>
<td>How often subject breaks diet to avoid telling others about diabetes &amp; -0.282 &amp; -3.37 &amp; 0.0010</td>
</tr>
<tr>
<td>How often feels diabetes limits career &amp; -0.183 &amp; -1.94 &amp; 0.0555</td>
</tr>
<tr>
<td>How often subject worries about passing out &amp; 0.246 &amp; 3.04 &amp; 0.0030</td>
</tr>
<tr>
<td><strong>Items included in model of satisfaction with diabetes control (type 2)</strong></td>
</tr>
<tr>
<td>Satisfaction with time managing diabetes &amp; 0.330 &amp; 6.11 &amp; &lt; 0.0001</td>
</tr>
<tr>
<td>Satisfaction with checkups time &amp; 0.095 &amp; 1.80 &amp; 0.0738</td>
</tr>
<tr>
<td>Satisfaction with current treatment &amp; 0.404 &amp; 7.84 &amp; &lt; 0.0001</td>
</tr>
<tr>
<td>Satisfaction with exercise time &amp; 0.161 &amp; 3.47 &amp; 0.0006</td>
</tr>
<tr>
<td>How often has pain with treatment &amp; -0.063 &amp; -1.31 &amp; 0.1913</td>
</tr>
<tr>
<td>How often subject worries about passing out &amp; 0.097 &amp; 2.10 &amp; 0.0364</td>
</tr>
<tr>
<td><strong>Items included in model of reported adherence with self-care regimen (type 2)</strong></td>
</tr>
<tr>
<td>Satisfaction with glucose maintenance time &amp; -0.237 &amp; -3.86 &amp; 0.0001</td>
</tr>
<tr>
<td>Satisfaction with diabetes knowledge &amp; -0.088 &amp; -1.46 &amp; 0.1467</td>
</tr>
<tr>
<td>Satisfaction with exercise time &amp; -0.251 &amp; -4.14 &amp; &lt; 0.0001</td>
</tr>
<tr>
<td>How often subject breaks diet to avoid telling others about diabetes &amp; -0.145 &amp; -2.45 &amp; 0.0151</td>
</tr>
<tr>
<td>How often subject worries about missing work &amp; -0.133 &amp; -2.10 &amp; 0.0372</td>
</tr>
<tr>
<td>How often subject worries about passing out &amp; 0.141 &amp; 2.26 &amp; 0.0248</td>
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corrected \( r = 0.97 \), and the weakest relationship was with the social worry scale (uncorrected \( r = 0.43 \) and corrected \( r = 0.52 \)). The final set of 15 items selected into the two regression models is shown in Table 3.

**DISCUSSION**

Research has suggested that individuals with diabetes have reduced HRQOL compared to the general population, but better HRQOL than individuals with many other chronic illnesses. While intensive insulin therapy has been successful in achieving control of the physical symptoms and complications of diabetes, patients report varied and mixed impact on their HRQOL. The goal of this study was to establish a reliable and valid brief DQOL inventory—focused on treatment satisfaction and compliance issues—that could be effectively integrated into clinicians’ office settings to improve patient-provider communication.

Previous HRQOL instruments, largely because of their length, have not transitioned from the research setting to provider office settings. To establish this shortened and treatment-focused inventory, we employed a statistically driven three-step process to identify the core set of items that is strongly linked to participants’ satisfaction with the diabetes control and their own self-care behaviors. The result was a 15-item shortened scale instrument that is highly correlated with the total DQOL and subscales. The shortened instrument was also able to explain as much variance in self-care behaviors and satisfaction with diabetes control as did the full DQOL. This suggests that we lost very little core information from the original DQOL subscales as a result of significantly shortening the survey.

A primary purpose for this shortened survey is to facilitate better communication between patients and their health care providers. The 15 items on this survey cover a broad range of issues related to diabetes. They range from satisfaction with various aspects of the diabetes regimen to fears and problems. One can easily imagine how these issues might not be uncovered during a typical clinical office visit. It is also easy to imagine how many of these issues could be addressed either through tailoring of the regimen, providing information, or simply listening and providing reassurance to patients’ concerns.

Because this was just the initial step in the development of a modified DQOL inventory, additional research will need to examine how to best integrate this measure into clinical practice and evaluate longitudinal...
reliability, predictive validity for clinical and QOL outcomes (particularly A1C levels), and responsiveness/sensitivity to different treatments. While the shortened scale has strong links to satisfaction with diabetes control and with self-care behaviors, there are several limitations that should be noted. First, with only 15 items, the instrument should be viewed as an initial screening device to identify specific patient issues, but does not obviate the need for informed probing of other issues that patients may be facing. Second, because the selection of items was driven by the statistical item relationships provided by the participants in this study, the extent to which these participants and their responses are not representative of the general population of people with diabetes may limit the generalizability of the instrument.

Despite these limitations, this study established a 15-item shortened version of the DQOL that demonstrated excellent ability to predict satisfaction and self-care behaviors, particularly among patients with type 1 diabetes. The items on the instrument cover a wide range of issues for people with diabetes that are addressable during routine clinical care. By identifying issues that might not otherwise come up during clinical care, the instrument provides an opportunity to strengthen the provider-patient interaction and provide patients with assistance for issues that may be impeding their HRQOL.

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