

Patient-assessed health outcome measures for diabetes: a structured review

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Abstract

Aims To identify available disease-specific measures of health-related quality of life (HRQL) for diabetes and to review evidence for the reliability, validity and responsiveness of instruments.

Methods Systematic searches were used to identify instruments. Instruments were assessed against predefined inclusion and exclusion criteria. Letters were sent to authors requesting details of further instrument evaluation. Information relating to instrument content, patients, reliability, validity and responsiveness to change was extracted from published papers.

Results The search produced 252 references. Nine instruments met the inclusion criteria: Appraisal of Diabetes Scale (ADS), Audit of Diabetes-Dependent Quality of Life (ADDQoL), Diabetes Health Profile (DHP-1, DHP-18), Diabetes Impact Measurement Scales (DIMS), Diabetes Quality of Life Measure (DQOL), Diabetes-Specific Quality of Life Scale (DSQOLS), Questionnaire on Stress in Diabetic Patients-Revised (QSD-R), Diabetes-39 (D-39) and Well-being Enquiry for Diabetics (WED). The shortest instrument (ADS) has seven items and the longest (WED) has 50 items. The ADS and ADDQoL are single-index measures. The seven multidimensional instruments have dimensions covering psychological well-being and social functioning but vary in the remainder of their content. The DHP-1 and DSQOLS are specific to Type 1 diabetes patients. The DHP-18 is specific to Type 2 diabetes patients. The DIMS and DQOL have weaker evidence for reliability and internal construct validity. Patients contributed to the content of the ADDQoL, DHP-1/18, DQOL, DSQOLS, D-39, QSD-R and WED. The authors of the ADDQoL, DHP-1/18, DQOL, DSQOLS gave explicit consideration to content validity. The construct validity of instruments was assessed through comparisons with instruments measuring related constructs and clinical and sociodemographic variables. None of the instruments has been formally assessed for responsiveness to changes in health.

Conclusions Five of the diabetes-specific instruments have good evidence for reliability and internal and external construct validity: the ADDQoL, DHP-1/18, DSQOLS, D-39 and QSD-R. Instrument content should be assessed for relevance before application. The instruments should be evaluated concurrently for validity and responsiveness to important changes in health.

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Keywords quality of life, diabetes mellitus, patient-assessed, review, validity, reliability

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Abbreviations ADS, Appraisal of Diabetes Scale; ADDQoL, Audit of Diabetes-Dependent Quality of Life; DHP, Diabetes Health Profile; DIMS, Diabetes Impact Measurement Scale; DQOL, Diabetes Quality of Life Measure; DSQOL, Diabetes-Specific Quality of Life Scale; D-39, Diabetes-39; QSD-R, Questionnaire on Stress in Diabetes-Revised; WED, Well-being Enquiry for Diabetics; HRQL, health related quality of life

Introduction

Diabetes can have a profound effect on quality of life in terms of social and psychological well-being as well as physical ill-health. It is one of the most psychologically demanding of the chronic diseases, with psychosocial factors pertinent to nearly every aspect of the disease and its treatment [1]. In a longitudinal study the psychosocial impact of diabetes was found to be one of the five strongest predictors of mortality in diabetic patients, stronger than many clinical and physiological variables [2].

Following diagnosis many patients experience psychological problems including social withdrawal, depression and anxiety. As the disease progresses psychosocial problems often occur secondary to the onset of complications, although several studies have reported an increased prevalence of depression and anxiety among patients irrespective of the presence of complications or loss of function [3]. Not just the disease but the treatment itself can exert a strong influence on quality of life. The control of symptoms of high blood sugar imposes restrictions on patients' quality of life as it often involves a prescriptive routine of diet, exercise, self-monitoring of blood and self-medication [4].

Patient-assessed measures of health outcome are increasingly used alongside traditional biomedical measures for the evaluation of treatment and management for diabetes [5]. The use of such instruments is particularly important in chronic conditions where a major objective of management is to arrest or reverse decline in function and quality of life. Given the wide-ranging effects that diabetes and its treatment can have on quality of life it is perhaps not surprising that there have been a large number of attempts to develop patient-assessed health outcome measures for diabetes.

It has been recommended that generic, disease-specific and situation-specific instruments are considered in the evaluation of patient-assessed outcomes for diabetes patients [6,7]. Generic instruments are designed to measure aspects of health that are of universal importance and are therefore suitable for comparisons between different groups of patients or healthy populations. Disease-specific instruments can include aspects of health considered by patients or clinicians to be of greatest importance. The targeted focus of disease-specific instruments has the potential to make them more responsive to changes in health and together with a more detailed and accurate assessment of patient concerns, this makes them important primary endpoints in clinical trials designed to measure changes in

health-related quality of life (HRQL). Situation-specific instruments have been developed to address specific situations and include measures of diabetes knowledge, attitudes and beliefs, management and self-care behaviour and treatment satisfaction [8].

There are a considerable number of patient-assessed measures of health outcome that are specific to diabetes. This can be confusing for clinicians and researchers who are interested in measuring the HRQL of patients with diabetes but are faced with several instruments offering different approaches to measurement. This timely review will provide potential users with structured evidence relating to the content and measurement properties of these instruments that will guide their future selection.

Methods

The focus of the review is patient-assessed disease-specific measures of HRQL for Type 1 and Type 2 diabetes mellitus. This includes instruments that measure multidimensional constructs including health status and health-related quality of life.

Search strategy

The search strategy was designed to retrieve references relating to the development of patient-assessed measures of health outcome for diabetes, including reviews of such instruments. Key journals including *Quality of Life Research* were hand-searched and various texts and compendia were consulted [9–12]. The search terms were developed by combining terms specific to patient-assessed health outcomes with diabetes-specific terms.

The following electronic databases were searched from 1980 to April 2000: AMED, Biological Abstracts, British Nursing Index, Cinahl, Embase, Econlit, Medline Express, Psychlit, Royal College of Nursing database and Sociological Abstracts. English language references were accepted. The names of identified instruments were used as terms for a further search of the electronic databases from 1980 to April 2001. Original papers were retrieved for references that included the development or evaluation of disease-specific patient-assessed health outcome measures. The citation lists of these papers were examined for references to previous developmental work and other instruments.

The first and second authors of identified instruments were sent a letter asking if they had produced other work relating to the instrument and requesting them to supply a copy of the questionnaire along with any scoring instructions. Reminders were sent at 1 month.

Inclusion criteria

Instruments were included in the review if they were patient-assessed, disease-specific with HRQL as the main focus. Instruments without some empirical evaluation of the measurement properties of reliability and validity were not included in the review. The review was restricted to instruments that have been evaluated in adult patients.

The review does not cover situation-specific instruments that have as their major focus constructs such as knowledge, attitudes and beliefs, management and self-care behaviour and treatment satisfaction. Instruments that solely measure diabetic complications were excluded. Furthermore, measures of diabetes symptoms were excluded from the review because they do not address broader patient concerns.

Data extraction

Information extracted from articles included the characteristics of patients in which the instrument was developed or evaluated, instrument content and the results of testing for reliability, validity and responsiveness. The information extracted followed that of previous reviews [9,13] and recommendations for instrument evaluation [14,15].

The characteristics of patients in which the instruments were developed and tested is described in terms of the data that were commonly available across studies including: setting, age, sex, diabetes type and disease duration.

The evaluation of instrument measurement properties includes tests of reliability, validity and responsiveness [14,15]. Reliability is concerned with whether an instrument is internally consistent or reproducible. Internal consistency is tested with a single administration of an instrument and assesses how well items within a scale measure a single underlying dimension. Test–retest reliability is designed to take account of variation over time in stable patients. The results of tests of internal consistency and test–retest reliability, specifically Cronbach's α and test–retest correlation coefficients, are presented. Reliability estimates of 0.7 and 0.9 are recommended for instruments intended for use in groups and individuals, respectively [15].

Validity is concerned with whether an instrument measures what is intended. Validity can be evaluated qualitatively through examination of instrument content and quantitatively through factor analysis and comparisons with related variables. Instrument content is typically based on some combination of literature reviews, patient and expert opinion [14,15]. Information relating to the source of instrument items together with any evidence for content and face validity is presented. These two forms of validity are qualitative matters of judging whether an instrument is suitable for its proposed application [15].

Factor analysis and principal component analysis provide empirical support for the dimensionality or internal construct validity of an instrument. Information relating to the use of these techniques is presented. External construct validation includes comparisons with other instruments and relating instrument scores to clinical and sociodemographic variables. The results of these comparisons were extracted. Expected correlations should be specified *a priori* [15]. Hypotheses relating to the direction and magnitude of coefficients are rarely presented and in their absence information was extracted for variables

that were found to have good evidence of a relationship with quality of life following a comprehensive structured review [16]. This review found that better quality of life was associated with: better glycaemic control; lower diabetic complications; male sex; younger age; marriage; and higher socioeconomic status.

Responsiveness refers to the ability of an instrument to measure important changes in health [15]. Responsiveness is assessed by looking at changes in instrument scores for groups of patients whose health is known to have changed. In the absence of formal tests of responsiveness developmental papers that incorporate longitudinal studies are included as evidence of instrument responsiveness.

Results

Search strategy

The initial search produced 846 references, of which 171 were potentially suitable for inclusion. The search using instrument names produced 405 references, of which 81 were potentially suitable for inclusion. Twenty instruments were identified and to assess whether they met the inclusion criteria published articles were reviewed and authors contacted with a request for a copy of the questionnaire and further information relating to instrument evaluation.

Nine instruments met the inclusion criteria. Of the remainder, three instruments had no published evidence for empirical validity [17–19]; two did not have HRQL as the main focus [20,21]; and two were measures of symptoms [22,23]. The Diabetes Quality of Life Clinical Trials Questionnaire [24] is not a distinct instrument but is largely a composite of generic and specific instruments including the SF-36 [25] and Diabetes Quality of Life Measure (DQOL) [26]. The Quality of Life Status and Change instrument is a generic instrument that has been partly tailored for Type 1 patients [27]. However, the nine diabetes-specific items mostly relate to situation-specific variables including diabetes management. The Social Psychological Health States was not developed specifically for diabetes but is designed for use across chronic conditions [28]. The Well-Being Questionnaire, although widely used in diabetes, is not diabetes-specific and focuses on psychological well-being [29]. These instruments were excluded from the review.

Patient characteristics

The populations in which the instruments have been developed or evaluated are shown in Table 1. The instruments have been evaluated within patient populations in the USA (4) [26,30–32], UK (2) [8,33], Germany (2) [34,35], Denmark (1) [5], Netherlands (1) [36] and Italy (1) [37]. The Diabetes-Specific Quality of Life Scale (DSQOLS) is the only instrument that has not been evaluated in both Type 1 and Type 2 diabetes patients.

Description of instruments

The dimensions covered by the six instruments are shown in Table 2. Items within the Appraisal of Diabetes Scale (ADS)

Table 1 Populations in which the instruments were evaluated

Instrument	Setting	<i>n</i>	Mean age (years)	Males <i>n</i>	Treatment/disease type (<i>n</i>)	Duration (years)
Appraisal of Diabetes Scale	USA out-patients [31]	200	58.4	200	Insulin (132)	15
Audit of Diabetes-Dependent Quality of Life	UK out-patients [33]	52	52.4	28	Insulin/diet (32), tablet/diet (14), diet (6)	12.7
	UK educational open day	102	61.6	55	Insulin/diet (38), tablet/diet (33), diet (30)	7.3
Diabetes Health Profile	UK out-patients [8]	239	40.9	—	Type 1/insulin requiring (239)	13.7
	UK out-patients [8]	2239	39.8	1144	Type 1/insulin requiring (2239)	13.1
	Out-patients [8]	233	51.5	121	Type 1/insulin requiring	—
	Netherlands out-patients [36]	99	61.2	48	Type 2	8.5
	UK out-patients [5]	532*	60.9	238	Type 2	—
	Denmark out-patients [5]	491	62.4–64.6	—	Type 2	—
Diabetes Impact Measurement Scales	USA out-patients [32]	130	45	55	Type 1 (51) Type 2 (77)	11
Diabetes Quality of Life Measure	USA out-patients [36]	192	—	114	Type 1	8
	USA out-patients [39]	240	52.6	118	Type 1 (111) Type 2 (129)	15.2
	USA out-patients [40]	170†	33.7	79	Type 1	16.6
Diabetes-39	USA out-patients [30]	516	52.4	240	Type 1 (159) Type 2 (330)	14.2
	USA out-patients	165	61.7	74	Type 1 (31) Type 2 (128)	11.5
	USA out-patients	262	55.3	93	Type 1 (25) Type 2 (218)	10.1
Diabetes Specific Quality of Life Scale	Germany general practice [34]	657	36	381	Type 1	18
Questionnaire on Stress in Patients with Diabetes-Revised	Germany in-patients and out-patients [35]	1930	—	1041	Type 1 (915) Type 2 (1015)	12.1
Well-Being Enquiry for Diabetics	Italy out-patients [37]	267	52.3	131	Type 1 (70) Type 2 (197)	7.1

*Data were missing on age, sex and treatment type for 101, 20 and 113 patients, respectively.

†The results reported in the study refer only to the 131 patients completing the DQOL.

Table 2 Instrument dimensions and number of items

Appraisal of Diabetes Scale	Audit of Diabetes-Dependent Quality of Life	Diabetes Health Profile*	Diabetes Impact Measurement Scales	Diabetes Quality of Life Measure	Diabetes-Specific Quality of Life Scale	Diabetes-39	Questionnaire on Stress in Patients with Diabetes-R	Well-Being Enquiry for Diabetics
Single index 7	Single index 13	Psychological distress 14 Barriers to activity 13 Disinhibited eating 5	Well-being 11 Social-role fulfilment 5 Diabetes-related morale 11 Non-specific symptoms 11 Specific symptoms 6	Worries about future effects of diabetes 4 Worries about social/vocational issues 7 Impact of treatment 20 Satisfaction with treatment 15	Worries about future 5 Social relations 11 Leisure time flexibility 6 Daily hassles 4 Diet restrictions 5 Physical complaints 8 Treatment satisfaction 10	Anxiety and worry 4 Social and peer burden 5 Sexual functioning 3 Energy and mobility 15 Diabetes control 12	Depression/fear of future 6 Leisure time 4 Partner 6 Work 6 Treatment regimen/diet 9 Physical complaints 6 Hypoglycaemia 4	Serenity 10 Discomfort 10 Impact 20 Symptoms 20

Doctor-patient relationship 4

*The number of items for the Diabetes Health Profile refers to the DHP-1. The DHP-18 has six, seven and five items for the psychological distress, barriers to activity and disinhibited eating dimensions, respectively.

and the Audit of Diabetes-Dependent Quality of Life (ADDQoL) sum to produce a single index. The remaining instruments have between three and eight dimensions. The dimensions of psychological and social well-being are covered by all the instruments and these health concepts are represented by items within the two single-index instruments. There is variation in the content of the remaining instrument dimensions.

The ADS aims to assess how a person with diabetes evaluates the disease and its impact [31]. Instrument content is based on theory and previous research. The seven items use a five-point scale and measure control, uncertainty, coping, affect of diabetes on life goals, predictive view of diabetes and the degree of distress caused by diabetes.

The ADDQoL is designed to measure individuals' perceptions of the impact of diabetes on their quality of life [33]. Instrument content was based on a review of existing instruments, discussions with health professionals and interviews with 12 diabetic patients. The ADDQoL comprises 13 items relating to physical functioning, symptoms, psychological well-being, social well-being, role activities and personal constructs. The items use a seven-point scale and ask patients how particular aspects of their life would be if they did not have diabetes (impact). Patients rate the importance of the aspects of their life on a four-point scale (importance). The two ratings are multiplied and summed to produce the final score.

The Diabetes Health Profile (DHP-1) was originally designed to identify psychosocial dysfunctioning among adult insulin-dependent and insulin-requiring patients in an ambulatory care setting [8]. DHP-1 content was derived following a literature review, a review of available instruments, interviews with 25 Type 1 and insulin-requiring patients and discussions with diabetes health care professionals [8]. The instrument comprises 32 items covering three dimensions: psychological distress, barriers to activity and disinhibited eating. Items use a four-point scale. The DHP-18 is an adaptation of the instrument for use in non-insulin-dependent patients [5]. Items that had poor endorsement frequencies or were of limited relevance to Type 2 patients were removed from the parent instrument.

The Diabetes Impact Measurement Scales (DIMS) is designed to measure longitudinal changes in health status in diabetes patients for application in clinical trials [32]. The DIMS was developed following a review of the literature and existing instruments and discussions with clinicians (physicians, a diabetes nurse and a dietician). The instrument comprises 44 items covering five dimensions: specific symptoms, non-specific symptoms, well-being, diabetes-related morale and social role fulfilment. Items use between four and six-point scales [32].

The DQOL was originally developed for use in a clinical trial comparing two treatment regimens for chronic complications in patients with Type 1 diabetes [26]. However, its structure allows application in Type 2 patients [6]. Instrument content was derived from three sources: a literature review identifying the concerns of diabetic patients and problems that impact on their lives; consultation with clinicians

Table 3 Instrument reliability

Instrument	Internal consistency		
	Item–total correlation	Cronbach's α	Test–retest correlation
Appraisal of Diabetes scale [31]	0.28–0.59	0.73	0.85–0.89
Audit of Diabetes Dependent Quality of Life [33]	0.37–0.67	0.84	—
Diabetes Health Profile	0.47–0.75 [8] ≥ 0.40 [5]	0.77–0.86 [8] 0.80–0.85 [8] 0.72–0.79 [36] 0.70–0.88 [5]	
Diabetes Impact Measurement Scales [32]	Data not shown	0.60–0.85	—
Diabetes Quality of Life Measure	—	0.67–0.92 [26] 0.52–0.88 [40] 0.47–0.87 [39]	0.78–0.92 [26]
Diabetes Specific Quality of Life Scale [34]	Data not shown	0.70–0.88	—
Diabetes-39 [30]	0.50–0.84	0.81–0.92 0.82–0.93 0.81–0.93	—
Questionnaire on Stress in Patients with Diabetes-Revised [35]	—	0.69–0.81	0.45–0.73
Well-Being Enquiry for Diabetics [37]	—	0.81–0.84	0.68–0.89

knowledgeable about diabetes; and patients with Type 1 diabetes. The instrument has 46 items that form four dimensions: satisfaction with treatment, impact of treatment, worries about future effects of diabetes, and worries about social and vocational issues.

The DSQOLS is designed to measure the quality of life of Type 1 diabetes patients [34]. The instrument also has a preference-weighted treatment satisfaction dimension. Instrument content was based on existing instruments and structured group discussions with Type 1 diabetic patients. The 39 quality of life items form six dimensions: social relations, leisure time flexibility, physical complaints, worries about the future, diet restrictions and daily hassles. Items use six-point scales.

The Diabetes-39 (D-39) is an evaluative instrument designed to assess the quality of life of patients with diabetes. Its purpose is to shed light on issues of importance to all diabetic patients and to determine unmet needs [30]. Instrument content was based on a literature review, existing quality of life instruments, and unstructured interviews with health professionals (physicians, diabetes educators, pharmacists) and diabetes patients. The 39 items cover dimensions of energy and mobility, diabetes control, anxiety and worry, social and peer burden and sexual functioning. Items use seven-point visual analogue scales.

The Questionnaire on Stress in Diabetic Patients-Revised (QSD-R) is designed to assess psychological stress associated with problems in daily living with diabetes [35]. The original QSD comprises 90 items selected following literature reviews and interviews with diabetologists and patients [38]. The instrument was revised on the basis of psychometric evidence and clinical experience. The QSD-R comprises 45 items that form eight dimensions: leisure time, depression/fear of future, hypoglycaemia, treatment regimen/diet, physical complaints, work, partner and doctor–patient relationship [35]. Patients

are asked whether a given statement applies to them and if so, to rate the extent to which daily stresses in that area cause them a problem on a five-point scale.

The Well-Being Enquiry for Diabetics (WED) is a measure of disease-related quality of life intended for application in different clinical settings [37]. Several diabetologists, psychiatrists, nurses and diabetic patients contributed to item development and some items were adapted from other instruments including the DQOL. The 50 items use five-point scales and form four dimensions: symptoms, discomfort, serenity and impact.

Reliability

Evidence of reliability is shown in Table 3. With the exception of the DQOL, QSD-R and the WED the instrument authors report the use of item–total correlation to assess scale homogeneity. Items should correlate at least 0.2 with the remainder of the scale [14,15]. The levels of Cronbach's α reported for studies evaluating the ADS, ADDQoL, DHP, DSQOLS, D-39 and WED exceed 0.7, the criterion recommended for studies involving groups of patients [15]. The DIMS dimension of specific symptoms had an α of 0.60 and the remaining scales ranged from 0.77 to 0.93 [32]. Two studies reported low levels of α for the DQOL dimension of social/vocational worry and two studies reported very low coefficients for diabetes worry [26,39–41]. Two QSD-R dimensions had borderline α coefficients [35].

The ADS and DQOL are the only instruments that have been adequately assessed for test–retest reliability. Reliability estimates for both instruments exceed criteria necessary for group evaluation [26,31]. The authors of the QSD-R and WED report poor and acceptable levels of test–retest reliability, respectively [35,37]. However, in both studies there was a

considerable gap between test and retest in which real changes in health may have occurred, and so these results must be interpreted with caution.

Validity

The authors of the ADDQoL, DHP-1, DQOL, DSQOLS gave consideration to content or face validity in instrument development [8,26,33,34]. Patients and diabetes experts were involved in the generation and confirmation of items within these instruments. The developers of the D-39, QSD-R and WED do not give explicit consideration to content or face validity but patients were involved in the generation of items [30,35,37]. Patients were not involved in the construction of the ADS and DIMS [31,32].

The DQOL was the only instrument not subjected to factor analysis or principal component analysis. Although a principal component analysis was performed on the DIMS there was no empirical support for the choice of dimensions used by the authors [32]. Factor analysis of the WED produced different dimensions but the original dimensions were retained for their clinical value [37].

Further tests of construct validity included correlation with other instruments and global judgements of health and comparisons with clinical and sociodemographic variables. The majority of studies did not present hypotheses relating to individual dimensions and external variables. The size of expected relationships was rarely hypothesized. The three DHP-1/18 evaluations described the expected relationships between individual dimensions, other instruments and clinical and sociodemographic variables [5,8,36]. Individual studies relating to the DQOL, D-39 and QSD-R described expected relationships with other patient-assessed measures [26,30,35]. However, the hypothesized strength of relationships was only described in four studies relating to the ADS, ADDQoL, DHP and DQOL [26,31,33,36].

Table 4 shows the results of these tests. The ADS scores had correlations in the hypothesized direction with scores for several situation-specific and dimension-specific instruments in the range 0.17–0.59 [31]. As hypothesized, ADDQoL scores correlated more highly with responses to a global judgement that was diabetes-specific rather than generic [33]. As hypothesized, the two DHP-1 dimension scores for psychological distress and barriers to activity had the largest correlations with scores for the Hospital Anxiety and Depression Scale and SF-36 [8]. Correlations between the DHP-1 dimensions of psychological distress and barriers to activity and SF-36 scales of social functioning, mental health, vitality and general health were mostly above 0.4 as hypothesized [36]. Correlations between DIMS scores and global judgements about general health were of a small to moderate magnitude [32].

In the original DQOL evaluation, 30 of the 40 correlations with scores for measures of psychological well-being and adjustment to illness were in the hypothesized range of 0.3–0.7 [26,41]. Two studies compared the DQOL with generic

instruments. In the first and against expectations, DQOL scores did not explain as much variation in disease indicators as generic instruments [40]. In the second study, total DQOL scores had small to moderate levels of correlation with SF-36 scales [39]. The DSQOLS dimension score had small to moderate levels of correlation with the Positive Well-being Scale [34]. The D-39 had the largest correlations with SF-36 dimensions that appear to measure similar constructs. The majority of correlations between the D-39 and global judgements about quality of life and diabetes severity were statistically significant [30]. Correlations between QSD-R scores and the Beck Depression Inventory and State-Trait Anxiety Inventory were of a small to moderate level [35]. The majority of the correlations between the WED and the DQOL, Hamilton Depression Rating Scale, State-Trait Anxiety Inventory and Bulimic Investigation Test Edinburgh were significant and of a small to moderate level [37].

All instruments have been compared with clinical and sociodemographic variables (Table 4). However, data were not reported for the D-39 [30]. There was a significant small level of correlation between ADS scores and HbA_{1c} [31]. ADDQoL scores were significantly correlated with perceptions of hypoglycaemia and the number of complications [33].

The developers of the DHP-1 hypothesized that women would score higher than men on two of the dimensions [8]. In the first sample women under 40 scored significantly higher than men on the psychological distress dimension, and women 65 years and under scored significantly higher on the disinhibited eating dimension. In the second sample women had a significantly higher mean score than men for the disinhibited eating dimension. A further study found that the hypoglycaemic complaint 'fatigue' was a significant predictor of DHP-1 scores for psychological distress and barriers to activity [36]. The disinhibited eating dimension scores were significantly related to age. There were no significant associations between DHP-1 scores and chronic complications [36]. As hypothesized, the DHP-18 scales of psychological distress and barriers to activity were significantly higher for insulin-treated patients compared with patients with less treatment demands. Furthermore, responses to individual items were significantly higher in insulin-treated patients. The disinhibited eating dimension scores were significantly correlated with age irrespective of treatment [5].

DIMS scores for non-specific symptoms, combined symptoms, well-being, diabetes-related morale and total DIMS scores were significantly correlated with HbA_{1c} levels [32]. DIMS scores were not significantly correlated with a diabetes complications index, although significant correlations were found for the total DIMS scores and symptom dimension for some individual diagnoses. Age was positively correlated with scores for two dimensions. Sex was related to scores for four dimensions and total DIMS scores [32].

The original DQOL evaluation found two significant associations with sex: women reported DQOL scores reflecting a greater impact of diabetes and greater diabetes-related worries [26]. In a comparison of the DQOL and generic instruments,

Table 4 Instrument validity

Instrument	Instrument	Clinical and sociodemographic variables
Appraisal of Diabetes Scale [31]	Diabetic Daily Hassles Scale $r = 0.59$ Diabetes Regimen Adherence Questionnaire-R $r = 0.17$ Diabetes Health Belief Questionnaire $r = 0.31-0.42$ Perceived Stress Scale $r = 0.49$ Psychiatric Symptom Index $r = 0.39-0.55$	HbA _{1c} $r = 0.18$
Audit of Diabetes-Dependent Quality of Life [33]	Global judgement (quality of life) $r = 0.31$ Global judgement (quality of life without diabetes) $r = 0.47$	Number of reported complications $r = 0.23$ Perceptions of hypoglycaemia $r = 0.32$
Diabetes Health Profile	Hospital Anxiety and Depression Scale $r = 0.28-0.62$ [8] SF-36 $r = 0.17-0.68$ [8] SF-36 $r = 0.07-0.65$ [36]	^a Sex ($P < 0.05$) [8] ^b Fatigue [36] Age [36] Complications (ns) [36] ^c Age $r = 0.04-0.49$ [5] Treatment ($P < 0.01$) [5]
Diabetes Impact Measurement Scales [32]	Global judgement patient (general health) $r = 0.27-0.47$ Global judgement clinician (general health) $r = 0.29-0.45$	Complications (ns) ^d HbA _{1c} ($P < 0.05$) Age ($P < 0.01$) Sex ($P < 0.01$)
Diabetes Quality of Life Measure	Symptom Checklist-90 $r = 0.40-0.60$ [26-41] Bradburn Affect Balance Scale $r = 0.27-0.57$ [26-41] Psychological adjustment to illness $r = 0.06-0.63$ [26-41] SF-36 $r = 0.00-0.60$ [39] ^e Duke Health Profile [40] General Health Perceptions Profile [40]	^f Sex ($P < 0.05$) [26] ^g Age $r = 0.34$ [39] Complications ($P < 0.01$) [39] ^h Marital status [39] Duration of disease (ns) [39] ⁱ Age ($P < 0.01$) [40] Sex (ns) [40] Marital status ($P < 0.01$) [40] Education level (ns) [40] Complications (ns) [40]
Diabetes Specific Quality of Life Scale [34]	Positive Well-Being Scale $r = 0.35-0.53$	^j HbA _{1c} $r = -0.24$ to 0.00 Age $r = -0.23$ to 0.00 Duration of disease $r = -0.22$ to 0.02 Age at onset of disease $r = -0.14$ to 0.09 ns Frequency of mild hypoglycaemia $r = 0.23-(-)0.03$ Social status $r = -0.04$ to 0.24 Type of insulin treatment ($P < 0.05$) Flexibility of insulin dosage ($P < 0.05$) Retinopathy ($P < 0.05$) Nephropathy ($P < 0.05$)
ⁱ Diabetes-39 [30]	SF-36 $r = 0.15-0.71$; $r = 0.20-0.71$ Global judgement of quality of life $r = 0.21-0.44$ Global judgement of diabetes severity $r = 0.15-0.56$	
Questionnaire on Stress in Patients with Diabetes-Revised [35]	^l Complications ($P < 0.05$) State-Trait Anxiety Inventory $r = 0.33-0.71$	Beck Depression Inventory $r = 0.39-0.67$ HbA _{1c} ($P < 0.05$)
Well-Being Enquiry for Diabetics [37]	Diabetes Quality of Life Measure $r = 0.05-0.68$ State-Trait Anxiety Inventory $r = 0.13-0.63$ Hamilton Depression Rating Scale $r = 0.29-0.49$ Bulimic Investigation Test Edinburgh $r = 0.26-0.35$	^m Complications ($P < 0.05$) ⁿ HbA _{1c} $r = 0.06-0.35$ ^o Age $r = 0.35$ ^p Sex ($P < 0.05$)

r , Correlation coefficient; ns, not significant.

^aStatistically significant for: DHP-1 psychological distress and disinhibited eating.

^bStatistically significant for: fatigue and DHP-1 psychological distress and barriers to activity; age and disinhibited eating.

^cStatistically significant for: treatment and DHP-18 psychological distress and barriers to activity; age and disinhibited eating.

^dStatistically significant for: HbA_{1c} and DIMS non-specific symptoms, combined symptoms, well-being, diabetes-related morale and total DIMS scores; age and well-being and diabetes-related morale; sex and non-specific symptoms and specific symptoms, well-being, diabetes-related morale and total DIMS scores.

^eRelative to the DQOL the generic instruments provided more information about HRQL and its relationship with diabetic and non-diabetic factors [40].

^fStatistically significant for: sex and DQOL diabetes-related worry, diabetes impact and total DQOL scores.

^gStatistically significant for: age and total DQOL scores; complications and treatment satisfaction, diabetes impact and total DQOL scores.

^hThe authors state that separated divorced or patients generally experienced worse quality of life than married patients.

ⁱStatistically significant for: age and DQOL social related worry; marital status and diabetes-related worry and social related worry.

^jStatistically significant for: HbA_{1c} and DSQOLS physical complaints, worries about the future and treatment satisfaction; age and leisure time flexibility and physical complaints; disease duration and leisure time flexibility and physical complaints; frequency of mild hypoglycaemia and treatment satisfaction; social status and physical complaints and diet restrictions; type of insulin treatment and leisure time flexibility, worries about future, diet restrictions; flexibility of insulin dosage according to carbohydrate intake and social relations, leisure time flexibility, worries about the future, diet restrictions; retinopathy and social relations, leisure time flexibility, physical complaints, worries about future; nephropathy and leisure time flexibility, physical complaints, worries about future.

^kD-39 scores were compared against clinical and sociodemographic variables but data were not reported.

^lStatistically significant for all but QSD-R scores for doctor–patient relationship.

^mStatistically significant for: complications and WED scores for symptoms and discomfort.

ⁿStatistically significant for Type 1 diabetes patient only.

^oCorrelation given for WED total scores only.

^pStatistically significant for total WED scores, symptoms and serenity in Type 2 patients.

four co-morbidity variables and psychosocial variables were sufficient to explain between 12% and 41% of variation in the DQOL impact and social/vocational worry dimensions, respectively [40]. Age entered the equation when DQOL dimension of social/vocational worry was the dependent variable; age was predictive of less social worry. Marriage entered the equation when the two DQOL worry dimensions and total DQOL scores were dependent variables; being married was predictive of higher quality of life. The DQOL developers also found that the DQOL total scores, impact and diabetes worry had a significant relationship with the number and severity of complications after controlling for age and marital status [39]. DQOL total scores were significantly correlated with age.

The DSQOLS scores for physical complaints and worries about the future had significant small levels of correlation with HbA_{1c} levels [34]. Dimension scores for leisure time flexibility, worries about the future and diet restrictions were significantly related to the type of insulin treatment. Dimension scores for social relations, leisure time flexibility, worries about the future and diet restrictions were significantly poorer for patients whose insulin dosage was in accordance with carbohydrate intake. The majority of dimension scores were significantly related to the presence of late complications. DSQOLS scores for leisure time flexibility and physical complaints had significant small levels of correlation with age and disease duration. Dimension scores for physical complaints and diet restrictions had significant small levels of correlation with social status.

QSD-R scores were significantly related to long-term complications and HbA_{1c} levels, the only exception being the dimension of doctor–patient relationship for the former [35]. WED scores for the dimensions of symptoms and discomfort were significantly related to complications [37]. There was a significant correlation between WED scores and HbA_{1c} levels for Type 1 diabetes patients. WED dimension scores for symptoms and serenity were significantly related to sex in Type 2 patients. Finally, WED total scores were significantly correlated with age.

Responsiveness

None of the nine instruments has been formally assessed for responsiveness. The author of the DQOL has looked at data

from two studies in support for the responsiveness of the instrument [41]. In the first, patients with end-stage renal disease were either given a kidney transplant or a combined pancreas and kidney transplant [42]. There was a significant improvement in the DQOL total scores and all subscales in patients who received the combined transplant, while there was no improvement for those that received the kidney transplant alone. The second study compared the quality of life of patients who received an implantable pump with those receiving normal insulin treatment [43]. The DQOL scale of satisfaction showed an improvement, but there were no other changes.

Two of the DHP-1 dimensions within an early version of the instrument were assessed for responsiveness in Type 2 patients changing to insulin treatment [44]. The psychological distress and barriers to activity dimensions produced standardized response means of 0.23 and 0.02. The authors of the DSQOLS cite an evaluation of a teaching programme for Type 1 diabetics as evidence for responsiveness [34,45]. Following the programme statistically significant improvements were found for the dimensions of social relations, physical complaints, worries about the future, diet restrictions and treatment satisfaction.

Discussion

The application of patient-assessed measures of health outcome in diabetes has continued to grow. However, comparability across evaluations including clinical trials has been hindered by the use of different instruments. During the last 15 years there have been numerous attempts to develop patient-assessed measures of health outcome for diabetes. This review has focused on disease-specific instruments that measure components of health-related quality of life.

With the exception of the DSQOLS, the instruments that were reviewed are intended for use in patients with Type 1 and Type 2 diabetes. The DHP-1/18 is the only instrument that has versions specific to both types of diabetes [5,8]. The DSQOLS is specific to Type 1 diabetes patients [34]. If a patient-assessed instrument is to have content validity as a measure that is relevant to the recipients of care, then patients should be involved in the derivation of items [15]. Patients were not involved in the development of items for ADS and DIMS. The authors of the

ADDQoL, DHP, DQOL and DSQOLS gave explicit consideration to content or face validity in instrument development.

The ADDQoL is the only instrument that is not based on the traditional psychometric approach to instrument development of summated rating scales. The ADDQoL includes an importance weighting for each of the items that sum to produce a single index.

The DQOL, DIMS and WED lack empirical support for dimensions that they purport to measure. The DQOL and DIMS have weaker evidence for reliability, while the remainder of the instruments produce reliability estimates that are acceptable for group comparisons including clinical trials. The interpretation of tests of construct validity was hindered by the limited use of formal hypotheses. The DHP-1/18 underwent the most rigorous testing for this form of validity. Hypotheses were also presented in the validation of the ADS, ADDQoL, DQOL, D-39 and QSD-R.

To date the greatest use of patient-assessed measures has been in the context of clinical trials and longitudinal evaluations of health care. The lack of testing for responsiveness to changes in health is a major shortcoming of patient-assessed measures for diabetes. The nine instruments reviewed here have not been formally evaluated for responsiveness. Future research should evaluate responsiveness through longitudinal comparisons of instruments within clinical trials or in relation to global judgements of changes in health.

The review has shown that there is variation in the content of the nine disease-specific instruments. Potential users should consider the content of instruments in relation to the patient population and research question. Furthermore, other domains are of potential importance to specific situations and clinicians and researchers interested in evaluating specific interventions should be aware of situation-specific instruments that measure constructs such as diabetes-related attitudes, behaviour and knowledge. Interventions designed to influence these factors are only desirable if they improve the quality of life of patients. Therefore patient-focused evaluation should include some measure of self-perceived HRQL. Consideration should also be given to the use of generic instruments which have greater potential to measure side or unforeseen effects of treatment and are useful for comparisons across patient populations.

Generic instruments that have been used with diabetes patients include the Nottingham Health Profile (NHP) [46], Short Form 36-item (SF-36) Health Survey [25], and the Sickness Impact Profile (SIP) [47,48]. However, both the NHP and the UK version of the SIP have been found to produce skewed responses towards positive health in diabetic patients [23,49]. This ceiling effect is likely to limit the responsiveness of these instruments, making them unsuitable for use as outcome measures in diabetes. The content of the SF-36 has been described as being mostly relevant to diabetes patients and there is evidence to support this suggestion [23,50].

The Well-being Questionnaire (WBQ) is a dimension-specific measure of psychological well-being that has had considerable

application in diabetes [10]. There is good evidence for reliability and validity of the WBQ, but as with other measures applied in diabetes, evidence for its responsiveness is limited. The WBQ is recommended where a detailed evaluation of psychological well-being is required for patients with diabetes.

In conclusion, on the basis of the extensiveness of supporting evidence, the ADDQoL, DHP-1/18, DSQOLS, D-39 and QSD-R offer the most promising approaches to patient-assessed measurement of disease-specific HRQL in diabetes. The development of these instruments involved diabetes patients. They have good evidence for internal reliability and internal and external construct validity. The developers of the ADDQoL, DHP-1/18 and DSQOLS also gave explicit consideration to content validity. However, there are still outstanding issues relating to the measurement properties and performance of these instruments. Instruments that are used longitudinally for purposes of evaluation should be assessed for test-retest reliability. The lack of evidence for responsiveness to change was the single most important failing of all the instruments included in this review and should be a priority for future research. Instruments should be used concurrently so that relative responsiveness and convergent validity can be evaluated. Such research will further inform decisions regarding the selection of instruments for applications, including clinical trials.

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