

Chapter 6: Patient-reported Health Instruments used for People with Diabetes

Introduction

Diabetes is a disorder of glucose metabolism caused by a lack of the pancreatic hormone insulin, which results in the accumulation of sugar in the bloodstream (hyperglycaemia) and the appearance of sugar in the urine. Symptoms include thirst, fatigue, weight loss, and excessive urination. The failure to metabolise glucose leads to the breakdown of fats in the body as an alternative source of energy; this process disturbs the acid-base balance in the body and results in the accumulation of ketones in the blood (ketosis) which, if untreated, can lead to convulsions, coma, and death.

There are two main categories of the disease: Type 1, or insulin-dependent diabetes mellitus (IDDM) and Type 2, non-insulin-dependent diabetes mellitus (NIDDM). In Type 1 diabetes, which begins in childhood or adolescence, genetic factors and autoimmune processes damage the insulin-producing (beta) cells in the pancreas, so that patients depend on insulin injections for their survival. Type 2, also called 'mature onset diabetes', generally appears after the age of 40 and also has a hereditary component; Type 2 diabetics usually retain some beta cell function but show insulin resistance, often exacerbated by obesity. In the initial stages of the disease, Type 2 diabetes may be treatable with a combination of diet and exercise alone; in more severe or advanced cases, oral hypoglycaemics and, eventually, insulin injections may be required.

Sufferers face many difficulties, notably self-management of what may be a very complex treatment regimen. Type 1 diabetics have to exercise careful control of their diet balanced with activity, in order to avoid a fall in blood sugar (hypoglycaemia) which can cause dizziness, confusion, and convulsions – symptoms ranging from the unpleasant to the terrifying, and potentially fatal. Patients receiving intensive insulin therapy may have to monitor their blood glucose and inject themselves several times a day. Type 2 diabetes may be asymptomatic at first, so that adherence to dietary restrictions and other lifestyle changes can seem unnecessarily burdensome. In the long term, both types of diabetes are associated with an array of complications, including repeated infections, cardiovascular and peripheral vascular disease, sexual dysfunction, kidney and nerve damage, and loss of vision. Diabetes is a leading cause of blindness, lower extremity amputation, and premature death.

Measuring health-related quality of life (HRQoL) as perceived by diabetic patients is essential if informed and rational choices are to be made amongst the wide range of treatments available, and in order to tailor these to the needs of individual patients. HRQoL measurement in diabetes presents particular challenges to researchers and health-care providers, given the complexities of the condition. There is considerable evidence to show that, in addition to the multiple physical impacts of the disease and its treatment, psychosocial factors, such as depression, social network, and family relationships, significantly affect the course of the disease, and vice versa (Davis et al., 1988; Rosenthal et al., 1998; Lustman et al., 2000). A plethora of measures has been developed for use with diabetes – a recent review (Skovlund, 2005) identified over 150 validated instruments – and choosing between them is far from straightforward.

The following review provides current information available of the patient-reported health questionnaires used to measure health-related quality of life with patients with diabetes.

Search terms and results: identification of articles

At the time of the review, the PHI database contained 12,562 records (up to June 2005). An initial search of record abstracts and titles using the term ‘diabet*’ generated 495 records, as shown in Table 6.1. All records were reviewed. When assessed against the review inclusion criteria, 187 articles were retrieved and reviewed in full. Of these, 90 articles were included in the review.

Table 6.1 Number of articles identified by the literature review

<i>Source</i>	<i>Results of search</i>	<i>No. of articles considered eligible</i>	<i>Number of articles included in review</i>
PHI database: original search (up to June 2005) Total number = 12,562	326	105	48
Additional PHI database search (July-December 2005) Total number = 4021	169	9	-
Supplementary searching		73	42
TOTAL	495	187	90

Supplementary searches included scanning the reference lists of key articles, checking instrument websites, where found, and drawing on other bibliographic resources. All titles of issues of the following journals published between January and September 2006 were scanned:

- Diabetes Care
- Health and Quality of Life Outcomes
- Medical Care
- Quality of Life Research

Identification of patient-reported health instruments

Five generic and six diabetes-specific instruments were included in the review. Instruments targeting paediatric or adolescent populations were excluded, as were those focusing on particular complications of diabetes, and instruments where there was no evidence that an English-language version had been tested. We aimed to include only those which have been applied with both main types of diabetes. The reviews of specific instruments drew substantially on a previous review by the PHIG (Garratt et al., 2002). Developmental and evaluative studies relating to the instruments reviewed are listed in Tables 6.2 to 6.14. Table 6.15 gives an overview of newly developed instruments and those where only one study was identified.

RESULTS: GENERIC PATIENT-REPORTED HEALTH INSTRUMENTS

Six generic instruments were identified which met the review criteria. Full details of the content and scoring methods are given in Chapter 3.

The measurement properties of the following instruments are reported:

- a) SF-36
- b) SF-12
- c) Sickness Impact Scale
- d) Health Utilities Index
- e) Quality of Well-Being Scale
- f) EuroQol- EQ-5D

a) SF-36

21 studies provided evidence of measurement properties for the SF-36.

Reliability

In a USA, outpatient clinic, internal consistency reliability scores for all subscales exceeded 0.70 (Jacobson et al., 1994). Similarly positive results were obtained in a UK study (Woodcock et al., 2001) and a second USA study (Wu et al., 1998).

Validity

In a large survey of the general population in eight countries, individuals self-reporting as having diabetes scored significantly worse on all dimensions of the SF-36 compared with respondents without chronic illness (Alonso et al., 2004). Similarly, in the Whitehall II study of over 10,000 civil servants, two scales of the SF-36, namely, General Health and Physical Functioning, showed significantly poorer scores for individuals with diabetes compared to the rest of the sample (Roberts et al., 1997).

In a study of patients with non-insulin-dependent diabetes, SF-36 scale scores were significantly related to number of complications but not to level of glycaemic control (Anderson et al., 1997). Significant correlations were also observed of SF-36 with severity and number of complications in a mixed study of type 1 and type 2 diabetes (Jacobson et al., 1994). In a national survey in the USA of individuals with diabetes, poorer scores for SF-36 were associated with a large number of other variables: less education, lower income, older age, being female, type of health insurance (no medical insurance or Medicare/Medicaid recipients reported lower quality of life than those with either a health maintenance organization or private insurance), number of diabetes complications, number of co morbid illnesses, and lower levels of physical activity (Glasgow et al., 1997). In a study of veterans patients with diabetes attending ambulatory clinics in Boston, SF-36 scales, especially Physical Function were significantly correlated with an index of diabetes severity (for example, eye and foot disease, atherosclerosis) Linzer et al., 2005). In a trial to improve management of patients with stable heart disease, those individuals who also had diabetes had significantly poorer SF-36 Physical Component Summary (PCS) and Mental Component Summary (MCS) scores than those individuals free of diabetes (Deaton et al., 2006).

A large randomly selected sample of the population in Adelaide was interviewed and also clinically assessed to identify individuals with diabetes (Chittleborough et al., 2006). Individuals with diabetes, compared with the rest of the sample were found to have poorer scores on all scales of SF-36 except Mental Health. These differences also obtained for previously undiagnosed cases of diabetes. Moreover individuals with impaired fasting glucose also had poorer Physical Functioning and Bodily Pain scales. All differences were after controlling for age, sex and cardiovascular disease. The authors also conduct effect size analyses to show that SF-36 identifies mainly small but important differences for all forms of impaired compared with normal glucose.

In a UK study, diabetes-related illness and a greater burden of diabetes treatment were related to poorer SF-36 scores (Woodcock et al., 2001). The SF-36 was included in a questionnaire-based survey of patients who had been patients of a large hospital in Cardiff (Currie et al., 2006). Presence of peripheral neuropathy-related symptoms was related to poorer SF-36 subscale scores. A small-scale study of men with diabetes in Seattle found only modest, but significant correlations between an objective measure of step-count and the physical activity scale of the SF-36 (Smith D.G. et al., 2004). A study comparing older with younger individuals with diabetes did not find predicted differences by age for SF-36 scores (Trief et al., 2003). A trial to evaluate effects of intensive treatment for insulin-dependent diabetes found that using SF-36 scores, there was no adverse effect on quality of life of more intense management (Diabetes Control and Complications [DCCT] Group, 1996). In a study comparing individuals with diabetes, epilepsy and multiple sclerosis, individuals with diabetes had more favourable scores for Mental Health and Role limitations due to Emotional problems (Hermann, 1996).

Responsiveness

In a longitudinal study of veterans with predominantly type 2 diabetes, the majority of SF-36 scales showed significant deterioration over the three years of observation (Ahroni and Boyko, 2000). Moreover, those who were found to have developed diabetic complications experienced significantly more deterioration than other patients. In a four-year follow-up study of individuals with various chronic illnesses, those with diabetes had a significant reduction in the PCS score of SF-36 compared with a reference group of individuals with hypertension only at baseline (Bayliss et al., 2004). In a small two-year RCT of nurse care management, whereas some small but significant improvements were noted for HbA_{1c}, triglycerides, and diastolic blood pressure, only the Vitality scale of SF-36 showed significant improvements (Hill-Briggs et al., 2005). The authors interpret these results as evidence of lack of responsiveness of the majority of scales. In another small RCT of alternative insulin regimens for individuals with poorly controlled diabetes, one of the regimens was associated with significant changes over time in several SF-36 scale scores either at three- or six-month follow-up (Hendra and Taylor, 2004).

Precision

A study of individuals with type 1 diabetes found that compared with HUI3, the SF-36 produced more skewed data and also a distribution that was closer to healthy normative data (Supina et al., 2006). The authors argued that the similarity of scores to healthy individuals ran counter to clinical expectations.

Acceptability

A 'desirable' level of response to the SF-36 of 70% was obtained in a UK study of diabetes sent out by post from general practices (Woodcock et al., 2001). In a very small-scale study of SF-36 in a nurse-led community clinic, although a positive overall report, it was reported that individuals with visual problems had difficulties completing the instrument (Hartley, 2002).

Feasibility

No specific results were found.

b) SF-12**Reliability**

No specific evidence was found.

Validity

In cross-sectional evidence, SF-12 some significant associations were found between patients' self-reported self-care and perceptions of quality of care, and SF-12 PCS and MCS scores (Aikens, Bingham, Piette, 2005). In a Canadian study, the SF-12 distinguished between individuals on different treatment regimes and groups with differing amounts of time off work, especially when scored by a Rasch-based method (Johnson and Maddigan, 2004).

Responsiveness

No specific evidence was found.

Precision

No specific evidence was found.

Acceptability

No specific evidence was found.

Feasibility

A study of SF-12 in a mixed sample of chronically ill subjects from across American medical practices included patients with diabetes (Liu et al., 2005). It showed that 31% of responses had at least one missing value but used modelling to conclude that missing values can be reliably inferred.

Table 6.2 Studies of diabetes using SF-36 and the SF-12

Study	Country (N) Age (years) Method of administration Setting	Measurement and Practical properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
Ahroni and Boyko (2000)	USA (331) Type 2 diabetes 63 Interview and questionnaire Outpatients			✓			
Alonso et al. (2004)	Eight countries (24,936) 44 Mixed mail and interview General population, including individuals self- reporting diabetes		Construct ✓				
Anderson et al. (1997)	USA (255) 63 Mail Hospitals in Michigan area	Internal consistency ✓	Construct ✓				
Bayliss et al. (2004)	USA (1574) 58 Mail Various HMO settings			✓			
Chittleborough et al. (2006)	Adelaide, Australia 4006 (266 with diabetes) Age (diabetes) 62 Administered by interview		Construct ✓				
Currie et al. (2006)	Cardiff, UK (1298) Age: type 1 55, type 2 70. Mailed questionnaires, self- completed		Construct ✓				

Study	Country (N) Age (years) Method of administration Setting	Measurement and Practical properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
SF-36							
Deaton et al. (2006)	USA, UK (1013) Age: 62 Patients with stable heart disease, with and without diabetes Interview at baseline of a RCT		Construct ✓				
Diabetes Control and Complication Trial Group (1996)	Various centres in USA (1441) IDDM Self-completed in clinic		Construct ✓				
Glasgow et al. (1997)	National survey USA (2056) Age 59 Type 1 and type 2 Postal survey		Construct ✓				
Hartley L. (2002)	USA (31) Age: 60 Interview Community-based nurse-led clinic	Internal consistency ✓	Construct ✓				
Hendra and Taylor (2004)	UK (57) Age: 69 Administered by nurse in clinic Clinic-based RCT			✓			
Hermann et al. (1996)	USA (555) Age: 59 Mailed Range of health service settings		Construct ✓				

Study	Country (N) Age (years) Method of administration Setting	Measurement and Practical properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
SF-36							
Hill-Briggs et al. (2005)	Baltimore USA (149) African-American type 2 diabetes RCT of nurse care management Administration not described			✓			
Jacobson et al. (1994)	USA (240) 44 (type 1) 60 (type 2) Type 1 and 2 diabetes Self-completed in clinic One outpatient clinic	Internal consistency ✓	Construct ✓				
Linzer et al. (2005)	Boston, USA (65) Age 64 Type 2 diabetes Mailed Primary care clinic		Construct ✓				
Roberts et al. (1997)	UK (10,308 of whom 65 have diabetes) Age 52 Self-completed questionnaire		Construct ✓				
Smith et al. (2004)	Seattle, USA (57) 68 Men with diabetes Clinic attendees		Construct ✓				
Supina et al. (2006)	Calgary Canada (216) 37 Type 1 diabetes Mailed to home Clinic		Construct ✓		✓		

Study	Country (N) Age (years) Method of administration Setting	Measurement and Practical properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
SF-36							
Trief P et al. (2003)	Syracuse, USA (191) Completed at clinic		Construct ✓				
Wu et al. (1998)	Wisconsin (143) 52 Type 1 diabetes Mailed from HMO	Internal consistency ✓					
Woodcock et al. (2001)	UK (184) Type 2 diabetes Mailed to home from general practice	Internal consistency ✓	Construct ✓			✓	
SF-12							
Aikens, Bingham, Piette (2005)	USA (752) Type 2 diabetes 63 Telephone interview Outpatients		Construct ✓				
Johnson and Maddigan (2004)	Alberta, Canada (372) Type 2 diabetes 62 Self-completed in clinic Outpatients		Construct ✓				
Liu et al. (2005)	USA (30,308) 53 Mixed chronically ill including diabetes Mailed to home						✓

c) Sickness Impact Profile

Reliability

A small-scale study of a sub-set of SIP subscales in individuals with diabetes found varying levels of test-retest reliability with lowest correlations for the Recreation and Pastimes scale (0.28) Bardsley et al., 1993).

Validity

A small-scale study of a sub-set of SIP subscales found satisfactory agreement with evidence from medical records of foot problems, angina and painful neuropathy, and body mass index (BMI) (Bardsley et al., 1993).

Responsiveness

No specific evidence was found.

Precision

No specific evidence was found.

Acceptability

No specific evidence was found.

Feasibility

No specific evidence was found.

Table 6.3 Study of diabetes using SIP

Study	Country (N) Age Method of administration Setting	Measurement and Practical properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
Bardsley et al. (1993)	UK (284) Interview Outpatient setting	Test re-test ✓	Construct ✓				

d) Health Utilities Index

Reliability

No specific evidence was found.

Validity

Maddigan and colleagues compared the performance of HUI2 and HUI3 as alternative scoring systems of a single 15-item questionnaire self-administered (Maddigan et al., 2003; Maddigan et al., 2004). While both scoring systems produced significant associations with clinical evidence such as type of treatment regimen and level of glycaemic control, differences were greater between clinical categories for HUI3 scoring. Maddigan and colleagues (2005) also examined patterns of HUI3 scores for individuals who self-reported diabetes in a Canadian national health survey

(Maddigan et al., 2005). Individuals self-diagnosing as having diabetes had somewhat lower HUI3 scores than healthy controls and further other co-morbidities increased the differences from health respondents. Similarly Bowker and colleagues (2006) found in another Canadian population health survey significantly poorer HUI3 scores for individuals with diabetes compared to healthy respondents, with cancer co-morbidity resulting in further reductions in HUI3 score. Wexler and colleagues (2006) found in a sample of type 2 diabetes patients that, with multiple regression analyses, microvascular complications, heart failure and depression were particularly strongly related to decreased HUI3 scores.

Responsiveness

No specific evidence was found.

Precision

No specific evidence was found.

Acceptability

No specific evidence was found.

Feasibility

No specific evidence was found.

Table 6.4 Studies of diabetes using HUI

Study/	Country (N) Age (years) Method of administration Setting	Measurement and Practical properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
HUI							
Bowker et al. (2006)	Canada (113,587) Self-completed population survey		Construct ✓				
Maddigan et al. (2003, 2004)	Alberta Canada (372) Age: 62 Type 2 Self-completed Trial of different services		Construct ✓				
Maddigan et al. (2005)	Canada (1193) Self-reported diabetes from survey		Construct ✓				
Wexler et al. (2006)	Boston USA (909) Type 2 diabetes Various types of clinic Supervised completion		Construct ✓				

e) Quality of Well-Being Scale

Reliability

In a small study within a clinical trial, Anderson and colleagues found high correlations between QWB scores, with assessments one day apart (Anderson et al., 1989).

Validity

Schwartz and colleagues administered the QWB in the context of a clinical trial evaluating glimepiride (Schwartz et al., 1999). They identified two distinct factors from items: observable limitations and subjective symptoms. In a study of type 1 and type 2 diabetes, QWB utility scores were significantly associated with frequency of hyperglycaemic symptoms and the occurrence of complications (Tabaei et al., 2004). In a study of type 1 and type 2 diabetes, major complications such as blindness, dialysis, symptomatic neuropathy, foot ulcers, amputation, debilitating stroke, and congestive heart failure were associated with lower utility scores in QWB (Coffey et al., 2002).

Responsiveness

No specific evidence was found.

Precision

No specific evidence was found.

Acceptability

No specific evidence was found.

Feasibility

No specific evidence was found.

Table 6.5 Studies of diabetes using Quality of Well-Being Scale

Study	Country (N) Age (years) Method of administration Setting	Measurement and Practical properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
Anderson et al. (1989)	California (76) Non-insulin-dependent diabetes Clinical trial	Test-retest ✓					
Coffey et al. (2002)	Michigan (2048) Type 1 and type 2 diabetes Self-completed University-based clinic		Construct ✓				
Schwartz et al. (1999)	California (588) Age:59 Non-insulin-dependent diabetes Mixed: self-completed and interview Clinical trial		Internal ✓				
Tabaei et al. (2004)	Michigan (1522) Age (type 1) 33 Age (type 2) 56 Self-completed Attendees of clinic		Construct ✓				

f) EQ-5D

Reliability

No specific evidence was found.

Validity

A postal survey of patients in the UK attending one of four centres with diabetes registers included the EQ-5D (Holmes et al., 2000). As well as showing that individuals with type 2 diabetes had poorer EQ-5D scores than the general population, the study showed that complications of diabetes were consistently associated with poorer EQ-5D scores. Patients at a large hospital in Cardiff were sent a questionnaire six weeks after discharge or at an outpatient clinic; the study included 2575 patients with diabetes (Lee et al., 2005). The EQ-5D, included as part of the questionnaire, showed significant differences between type 1 and type 2 diabetes and significantly poorer utility scores with increased BMI.

Responsiveness

The EQ-5D was used as an outcome measure in the UK Prospective Diabetes Study RCT to evaluate benefits of tighter control of blood glucose level and blood pressure (UKPDS Group, 1999; Clarke et al., 2002). While tighter control had significant benefits in reducing complications, there were no differences between standard and more intensive treatment on the EQ-5D. However complications were significantly associated with poorer EQ-5D scores. The authors comment on the skewed nature of EQ-5D scores in analyses.

Precision

Bharmal and Thomas (2006) examined patterns of responses to EQ-5D and SF-6D in a general population survey, the 2000 Medical Expenditure Panel Survey, including respondents with diabetes. Up to 49% of those individuals with no problems identified on EQ-5D reported some negative items on SF-6D, leading the investigators to infer that EQ-5D had important ceiling effects.

Acceptability

No specific evidence was found.

Feasibility

No specific evidence was found.

Table 6.6 Studies of diabetes using EQ-5D

Study	Country (N) Age (years) Method of administration Setting	Measurement and Practical properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
Bharmal and Thomas (2006)	National health survey in USA (5104) with sub-sample with diabetes		Construct ✓		✓		
Holmes et al. (2000)	Four diabetes centres in UK (1578) Type 2 diabetes Age: 67 Self-completed from mailed questionnaire		Construct ✓				
Lee et al. (2005)	Cardiff (2575) Age: Type 1: 52, type 2: 68 Self-completed, mailed from hospital Discharged patients		Construct ✓				
UKPDS Group (1999)	UK (3104) Type 2 diabetes Age: 52 (self-completed in clinic)		Construct ✓				

Miscellaneous measures

Two generic measures, the Duke Health Profile (DUKE) and the General Health Perceptions Questionnaire (GHP) were both examined in a sample of 170 insulin-dependent patients with diabetes from a number of American clinics (Parkerson et al., 1993). Scales of the two instruments were treated as dependent variables in regression analyses. Aspects of diabetes (duration, complications, and severity of treatment) were not generally predictors of scales of either instrument, and stronger associations were found between socio-demographic and psychosocial factors and scales of the two instruments.

Hornquist and colleagues developed a system for rating the quality of life of individuals with diabetes, based on an initial study of 73 patients recruited in 1988 (Hornquist et al., 1993; Hornquist et al., 1995). However descriptions of the instrument are not clear and it is not apparent that the instrument has evolved into a stable form that can be considered for routine use. It is described as a generic instrument.

An Australian study was carried out of a modified version of the Patient Generated Index, termed 'the Client Generated Index' (CGI) (Griffiths et al., 2000). The CGI required trained interviewers to administer. High levels of test-retest reliability were found over a five-week period. Correlations with subscales of the SF-36 provided some evidence of construct validity.

The Behavioral Risk Factor Surveillance System (BRFSS) is a periodic national survey carried out by telephone interview in the United States. A study showed that nine questionnaire items from the BRFSS identified areas of quality of life in terms of which respondents with diabetes scored significantly worse than controls (Smith D.W. 2004).

RESULTS: DIABETES-SPECIFIC PATIENT-REPORTED HEALTH INSTRUMENTS:

Six specific instruments were identified which met the review criteria. Full details of the content and scoring methods are given in Tables 6.7 and 6.8.

The measurement properties of the following instruments are reported:

- a) Appraisal of Diabetes Scale/ADS
- b) Audit of Diabetes-Dependent Quality of Life/ADDQoL
- c) Diabetes 39/D-39
- d) Diabetes Health Profile/DHP
- e) Diabetes Quality of Life Measure/DQOL
- f) Diabetes Quality of Life Clinical Trial Questionnaire/DQLCTQ

a) Appraisal of Diabetes Scale/ADS

The ADS is a brief self-report questionnaire which assesses an individual's thoughts about coping with diabetes (Carey et al. 1991). It was developed in light of 'the transactional relationship between stress and diabetes' – the fact that whilst external stressors can disturb glucose metabolism, hence the course of the disease, adherence to a strict diabetic regime can of itself be stressful. The authors suggest that the ADS may be useful as a screening instrument for adjustment to diabetes, specifically to identify those patients experiencing, or at risk for, dysphoric reactions and problems of adherence to their diabetic regime. The content of the scale is based on theory and research regarding appraisal processes; some items were adapted from a generic Attribution Questionnaire (Hammen and Mayol, 1982).

The instrument consists of seven items covering distress caused by diabetes, control over diabetes (two items), uncertainty due to diabetes, anticipated future deterioration, coping, and effect of diabetes on life goals. The items use a five-point adjectival scale scored from 1 (e.g. control – none at all) to 5 (control – total amount). ADS items are summed to produce a score from 0-35, 0 representing the least and 35 the greatest impact of diabetes.

b) Audit of Diabetes Dependent Quality of Life/ADDQoL

The ADDQoL is an individualized instrument designed to measure an individual's perceptions of the impact of diabetes on their quality of life (Bradley et al., 1999; Speight & Bradley, 2000; Bradley & Speight, 2002). The intention was to create a detailed version for research and in-depth clinical work, and a short form for audit purposes. No further information has been found regarding the latter.

The instrument comprises 18 (originally 13) items where the respondent is invited to indicate, firstly, the effect of diabetes on a particular aspect of life (for example, enjoyment of food, ease of travelling) and, secondly, how important this aspect of life is to overall quality of life. Three (originally ten) of the items – namely, family life, working life, and sex life - have a 'not applicable' response option, allowing patients to exclude items which are not relevant to them. Patients respond by circling a number on a seven-point scale which asks how a particular aspect of their life would be if they did not have diabetes (from -3: 'very much better' to +3: 'very much worse'). They then rate the importance of this aspect of their life on a four-point scale (from 3: very important, to 0: not at all important). Impact ratings are multiplied by importance

ratings to produce a -9 to +9 score, then summed and divided by the number of applicable domains to produce a final score from -9 to +9.

In the original version of the ADDQoL, two additional summary items asked respondents to rate their general QoL, and what their QoL would be if they did not have diabetes, each on a seven-point verbal rating scale. The revised version has a single summary item measuring 'present quality of life' on a seven-point scale from -3 (extremely bad) to +3 (excellent). The wording has also been simplified and amended in order to reduce the number of 'non-applicable' items.

c) Diabetes 39/D-39

The authors of the D-39 intended it to have 'range and reliability', in other words, to be highly relevant to a wide range of diabetes patients over time, easy to use and understand, and to possess good psychometric properties (Boyer and Earp, 1997). A slightly modified version has been developed for use in clinical trials.

The D-39 comprises 39 items in five domains, namely energy and mobility (15 items), diabetes control (12 items), anxiety and worry (four items), social and peer burden (five items), and sexual functioning (three items). Scores are marked on seven-point visual analogue scales ranging from 'not affected at all' to 'extremely affected', then transformed linearly to 0 to 100 scales.

d) Diabetes Health Profile/DHP

The DHP-1 is a multidimensional self-completion instrument originally designed to identify psychosocial dysfunction among adult insulin-dependent and insulin-requiring patients in an ambulatory care setting (Meadows et al., 1996). The instrument has also been adapted for use in non-insulin dependent patients (Meadows et al., 2000). Content was derived from a literature review, a review of available instruments, interviews with IDDM and insulin-requiring patients, and discussions with diabetes health-care professionals (Meadows et al., 1996).

The DHP-1 comprises 32 items covering three dimensions: psychological distress (14 items), barriers to activity (13 items), and disinhibited eating (5 items); it is suggested this last may be appropriate as a screening tool for eating problems. Each item has a four-point adjectival scale; items are summed within the three dimensions and transformed to produce a score from 0-100 where 0 represents no dysfunction.

e) Diabetes Quality of Life Measure/DQoL

The DQoL was originally developed for use in a clinical trial comparing the efficacy of two different treatment regimens on the appearance and progression of chronic complications of patients with IDDM (DCCT Research Group 1988). However its structure allows for application to other patients with IDDM and NIDDM. The developers state that the DQoL could be used in clinical settings as a screening measure to identify patients with concerns about diabetes.

The instrument has 46 core items forming four scales: satisfaction with treatment (15 items), impact of treatment (20 items), worries about future effects of diabetes (four items), and worries about social and vocational issues (seven items). The instrument also includes a generic health item that does not contribute to the scales. Adolescent and youth versions of the DQoL have been developed (Ingersoll and Marrero, 1991).

The dimensions and DQoL total scores (average score across the four dimensions) are scored 0-100 where 0 represents the lowest possible quality of life and 100 the highest.

f) Diabetes Quality of Life Clinical Trials Questionnaire-Revised/DQLCTQ-R

The DQLCTQ was developed for use in multinational clinical trials of patients with IDDM and NIDDM (Shen et al., 1999). It was developed and published alongside a revised version of the instrument referred to as the DQLCTQ-R. The DQLCTQ comprises 142 items across 20 domains, three self-efficacy questions and four demographic questions. For the most part, items use five-point adjectival scales. The DQLCTQ-R, comprises 57 items across eight domains, with between three and ten response options. Mean scores for each domain are transformed into a 100-point scale where higher scores represent better quality of life.

Miscellaneous measures

Several diabetes-specific instruments with a very particular focus have been developed, for example, the Insulin Delivery System Rating Questionnaire (Peyrot and Rubin, 2005) described by the authors as a measure of HRQoL and treatment preference, and the Confidence in Diabetes Self-care scale (Van der Ven et al., 2003) which aims to assess a person's perceived ability to manage their condition. Culturally sensitive measures have also been developed for use with particular ethnic groups, given the higher prevalence of diabetes and greater incidence of long-term complications in, for example, African Americans as compared with 'European' Americans (Elasy et al., 2000). Although such specifically-focused instruments may have merit in targeted research studies, they are not included in this review.

More numerous still are diabetes-specific measures of psychosocial functioning. This is hardly surprising given that diabetes has been described as one of the most psychologically demanding of chronic illnesses (Cox and Gonder-Frederick, 1992). The best-known of these measures is the Well-Being Questionnaire/WBQ developed by Clare Bradley and colleagues (Bradley and Lewis, 1990) which measures depression, anxiety and, notably, positive well-being. Although not intrinsically specific to diabetes, this measure has been so widely used with diabetic patients; it is generally regarded as such. It is often used in conjunction with the Diabetes Treatment Satisfaction Questionnaire (Bradley and Lewis, 1990), developed concurrently with the WBQ.

Other such measures include the ATT39 (Dunn et al., 1986) which assesses emotional adjustment in diabetic patients, the Problem Areas in Diabetes scale/PAID (Polonsky et al., 1995) measuring diabetes-related distress, and the Fear of Hypoglycaemia Survey/HFS (Cox et al., 1987), developed in response to the phenomenon of insulin-dependent patients whose fear of hypoglycaemic episodes leads them to maintain undesirably elevated levels of blood glucose. Also noteworthy is the Diabetes Care Profile (Fitzgerald et al., 1996), a lengthy (234-item) survey instrument to assess the social and psychological factors related to diabetes and its treatment, which has been tested for reliability with a minority ethnic population (Fitzgerald et al., 1998). Again, this group of measures, whilst undoubtedly of importance, is beyond the scope of the present review.

DIABETES-SPECIFIC INSTRUMENTS: Domains, items and scoring methods

Table 6.7 Diabetes-specific patient-reported health instruments

<i>Instrument (no. items)</i>	<i>Domains (no. items)</i>	<i>Response options</i>	<i>Score</i>	<i>Administration/ Completion (time)</i>
Appraisal of Diabetes Scale/ADS	<i>Single index (7)</i> Distress Control (2 items) Uncertainty Future condition Coping Impact on life goals	5-point adjectival scales: 1 (not at all) to 5 (extremely/totally)	Scale scores summed to give an overall total 0-35	5 mins
Audit of Diabetes-Dependent Quality of Life/ADDQoL	<i>18 items:</i> Freedom to eat as I wish Enjoyment of food Family life* Working life* Sex life* Physical activity Worries about the future Holidays/leisure activities Freedom to drink as I wish Self-confidence Friendships, social life Motivation to achieve things Ease of travelling Physical appearance Finances Living conditions Unwanted dependence on others Reaction of society <i>1 summary item: Present QoL</i>	Impact: -3 (very much better without diabetes) to +3 (very much worse) Importance: 0 (not at all important) to 3 (very important) 3 items with N/A option (*)	Impact x importance = weighted score (range -9 to +9). Scores for each item summed, then divided by no. applicable items to give average weighted impact (AWI) score (i.e. N/A items do not contribute to score).	<10 mins
Diabetes 39/D-39	<i>39 items:</i> Anxiety and worry (4) Social and peer burden (5) Sexual functioning (3) Energy and mobility (15) Diabetes control (12)	7-point visual analogue scales; 1 = not affected at all, 7 = extremely affected	Scores transformed into 0-100 scores; 0 – lowest, 100 – highest possible score	<i>Not reported</i>

<i>Instrument (no. items)</i>	<i>Domains (no. items)</i>	<i>Response options</i>	<i>Score</i>	<i>Administration/ Completion (time)</i>
Diabetes Health Profile/DHP 1/18	Psychological distress (14/6) Barriers to activity (13/7) Disinhibited eating (5/5)	Four-point adjectival scales	Item scores 0-3 in each dimension summed & transformed to produce score between 0 (no dysfunction) and 100	<i>Not reported – probably 5-10</i>
Diabetes Quality of Life Measure/ DQOL	Worries - future effects of diabetes (4) Worries - social/vocational issues (7) Impact of treatment (20) Satisfaction with treatment (15)	5-point Likert scale	<i>No details</i>	15- 20 minutes
Diabetes Quality of Life Clinical Trials Questionnaire-Revised/ DQLCTQ-R	<i>57 items in 8 domains:</i> Physical function Energy/fatigue Health distress Mental health Satisfaction (DQOL) Treatment satisfaction Treatment flexibility Frequency of symptoms <i>1 global health question</i> <i>1 transition question</i>	Variety of ordinal scales, with 3 to 10 response options.	Mean scores for each domain converted to a 100-point scale	'10 mins' – probably 15-20

Table 6.8 Summary of diabetes-specific instruments: health status domains

<i>Instrument</i>	<i>Instrument domains (after Fitzpatrick et al., 1998)</i>								
	Physical function	Symptoms	Global judgment	Psychological well-being	Social well-being	Cognitive functioning	Role activities	Personal constructs	Treatment satisfaction
Appraisal of Diabetes Scale/ADS				x	x		x	x	
Audit of Diabetes-Dependent Quality of Life/ADDQoL	x			x	x		x	x	
Diabetes 39/D-39	x			x	x			x	
Diabetes Health Profile/DHP 1/18				x	x		x		
Diabetes Quality of Life Measure/DQOL		x		x	x		x		x
Diabetes Quality of Life Clinical Trials Questionnaire-Revised/DQLCTQ-R	x	x	x	x	x		x	x	x

DIABETES- SPECIFIC PATIENT- REPORTED HEALTH INSTRUMENTS

a) Appraisal of Diabetes Scale/ADS

Reliability

Internal consistency

Item-total correlations were adequate: in the range of 0.28-0.59. Cronbach's alpha was 0.73, demonstrating sufficient reliability for use in groups. Principal component analysis yielded a single dimension; all items had loadings above 0.40. These analyses indicate the scale assess an internally consistent dimension of diabetes appraisal (Carey et al., 1991). Test-retest reliability was assessed by giving the ADS to a sub-sample of patients (n = 98) on three occasions: just before blood withdrawal, one hour after completing clinic visit, and one week later. Pearson product moment correlations for the one-hour and one-week retest were 0.89 and 0.85, respectively, demonstrating stability.

Validity

Convergent validity

Positive correlations were expected with measures of negative affect (anxiety, anger, and depression), perceived stress, diabetes-related hassles, perceived severity of diabetes/susceptibility to complications, and non-adherence to the diabetic regimen. A second sub-sample of patients (n = 102) was asked to complete these measures. Strong relationships were found between ADS scores and measures of negative affect, perceived stress, and diabetes-related hassles (Pearson product moment correlations 0.39-0.59). A modest relationship was found between the ADS and the measure of adherence (0.17), suggesting that patients reporting negative appraisal were less likely to adhere to their diabetic regimen.

Criterion validity

A low correlation (0.18) was found between ADS scores and the standard measure of glycaemic control, HbA_{1c} (glycosylated haemoglobin), indicating that those reporting negative appraisal were more likely to have experienced poor glycaemic control during the weeks prior to the test. Further studies have used the ADS as part of a battery of measures including the SF-36 and the DQOL, to examine the impact of family systems (Trief et al., 1998) and the work environment (Trief et al., 1999) on glycaemic control and psychosocial adaptation. Both studies found that the ADS strongly predicted glycaemic control and, in the 1998 study, scores on all DQOL subscales, and SF-36 role-physical, role-emotional, and bodily pain domains.

In the 1999 study, having more complications, older age, and shorter duration of diabetes were significant predictors of more negative appraisal on the ADS, whilst greater perceived supervisor support significantly predicted more positive appraisal. This study appeared to show inconsistent findings in that older age predicted more negative appraisal (ADS) but greater diabetes-related satisfaction (DQOL). However, it was concluded that the two measures tap into different aspects of adaptation: the DQOL satisfaction subscale assessing primarily current satisfaction with the diabetes care regimen, whilst the ADS focuses on coping efficacy in the present but uncertainty about the future.

Paradoxically, in a more recent study to compare the HRQoL of elderly and younger persons with diabetes (Trief et al., 2003), using the same array of instruments plus the PAID, the elderly group reported significantly better appraisal of diabetes (ADS) despite having more role limitations due to physical problems (SF-36). The authors hypothesize that this may reflect a cohort phenomenon, and acknowledge other potential confounders (e.g. specific complications, non-diabetic co-morbidities). Trief et al. also contend that diabetes-specific measures, including the ADS, have not included elderly patients in validation samples so that they may not be truly valid with the over-65 age-group; they suggest that future research should explore the validity of existing measures and pursue the development of diabetes-specific HRQoL measures specifically relevant to elderly individuals.

Responsiveness

No specific evidence was found.

Acceptability

The majority of patients found the instrument quick and easy to complete, requiring five minutes or less. In the initial study, of the 98 patients asked to complete the ADS on three occasions, 79% returned complete retest data.

Feasibility

No specific evidence was found.

Table 6.9 Developmental and evaluation studies relating to the Appraisal of Diabetes Scale/ADS

Study Reference Country	Population & setting (n) Age; male/female Type 1/Type 2; duration Method of administration	Measurement properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
Carey et al. (1991) USA	Diabetic outpatients (200) Mean age 58.4; all M 66% T1; duration 15 yrs Self-report; 1-week retest mailed to home	Internal consistency ✓ Test-retest ✓	Convergent ✓			✓	✓
Trief et al. (1998) USA	Diabetes clinic patients (150) Mean age 51, range 20-79 M 84 (56%), F 66 (44%) T1 81 (54%) T2 68 (46%); duration 15.6 yrs. White 97% Self-report after clinic visit/at home, returned by mail. Battery incl. SF-36, DQOL, WBQ, ADS & family system measures		Criterion ✓				
Trief et al. (1999) USA	Diabetics in employment (129) Mean age 40.5, range 19-70 M 68 (53%), F 61 (47%) T1 93 (72%) T2 35 (27%); duration 14 yrs White 96% Self-report after clinic visit. Battery: DQOL, ADS & work systems measures		Criterion ✓				
Trief et al. (2003) USA	Diabetes clinic patients, all insulin users (191) a) 30-64 yrs (100); M 51, F 49 T1 52, T2 48; duration 13.5 yrs White 96% b) >= 65 yrs (91); M 46, F 45 T1 18, T2 73; duration 18.3 yrs White 93% Self-report battery: SF-36, DQOL, PAID, ADS		Criterion ✓				

b) Audit of Diabetes Dependent Quality of Life/ADDQoL

Reliability

The original design of the ADDQoL was influenced by the principles underlying development of the interview measure, the Schedule for the Evaluation of Individual Quality of Life/SEIQoL (McGee et al., 1991), as well as discussions with health professionals, and in-depth interviews with diabetic patients. The content was then reviewed by the British Diabetic Association/Royal College of Physicians Working Group, and patients with diabetes. Further development of the instrument, with the addition of items aiming to extend its relevance to people with complications of diabetes, has resulted from work on the Renal-Dependent Quality of Life/RDQoL (Bradley, 1997).

Evidence for the unidimensionality of the 18-item instrument (Speight & Bradley, 2000) was found through a forced one-factor analysis; all 18 items had factor loadings above 0.5. Item-total correlations for the original 13-item version ranged 0.37 to 0.67 (item-total correlations for the 18-item version not found). Cronbach's standardized item alpha for the 18-item instrument was 0.92, indicating high reliability (Speight and Bradley, 2000). No evidence was found for test-test reliability.

In the original development study (Bradley et al., 1999), six of the ADDQoL items elicited responses which indicated positive effects of diabetes, illustrating the need for bipolar scales to measure the impact of diabetes. All four importance ratings were used for the 13 domains. The authors cite this as evidence in support of the importance ratings, which take individual perceptions of impact on QoL into account.

In the original study (Bradley et al., 1999), mean weighted ADDQoL scores were correlated with the two summary items and, as hypothesized, correlated better with the diabetes-specific item ($r = 0.47$) than with the generic item ($r = 0.31$); both were highly significant. The correlations fell well below 1.00, indicating that ADDQoL scores provided information additional to that elicited by the summary items.

Validity

Clinical and QoL variables

ADDQoL scores were significantly correlated with perceptions of hypoglycaemia ($r = 0.32$) and the number of reported complications ($r = 0.21$). As hypothesized, ADDQoL scores showed a greater negative impact of diabetes on quality of life for insulin-treated patients. This difference was significant for seven out of 13 dimensions (Bradley et al., 1999).

Generic health status measures

A study by Woodcock et al., (2001) compared the performance of an 11-item version of the ADDQoL and the SF-36 in a group of patients with Type 2 diabetes, and concluded that the two were complementary. The authors found that ADDQoL scores were skewed towards good general QoL, although indicating a negative impact of diabetes. Correlations between the two instruments were greater amongst patients with diabetes alone, compared with patients reporting non-diabetic co-morbidity.

Responsiveness

A study reporting the DAFNE (dose adjustment for normal eating) trial of a five-day education programme, which aimed to teach patients how to match their insulin dose to food choices, found significant improvements in the negative impact of diabetes on dietary freedom, as measured by the 'Freedom to eat as I wish' item, and in the impact on general quality of life, measured by the summary item. For the former, the improvement was apparent at six months follow-up; for the latter it reached significance by one year (DAFNE Study Group, 2002).

Precision

The authors argue that the use of importance ratings to weight item scores prevents the impact of particular items from being either under- or overestimated in the individual case, enhancing precision (Bradley et al., 1999).

Acceptability

The principle behind the ADDQoL is to enable patients to show how diabetes affects them as an individual, allowing them to give added weight to those aspects which are particularly important to them. However, it has been argued (Polonsky, 2000) that the stem question of the scale ('If I did not have diabetes, [x aspect of my life] would be [from 'a great deal better' to 'a great deal worse']') represents a complex cognitive task, somewhat removed from direct questions about diabetes-specific QoL. On the other hand, it offers respondents the chance to indicate areas where they feel diabetes may have had a positive impact.

Response rates for the original samples ranged between 62% and 93%. Missing data for the three items presumed to relate to everyone, namely physical activity, motivation, and enjoyment of food, ranged from 3% to 8% (Bradley et al., 1999). In the Woodcock study (Woodcock et al., 2001), response rates exceeded 70%. It is estimated the instrument takes under ten minutes to complete.

A recent study in Singapore (Wee et al., 2006) found the ADDQoL to be culturally appropriate for English-speaking Chinese, Indian, and Malay patients, as well as confirming the reliability, validity, and acceptability of the instrument.

Feasibility

No specific evidence was found.

Table 6.10 Developmental and evaluation studies relating to the Audit of Diabetes-Dependent Quality of Life/ADDQoL

Study Reference Country	Population & setting (n) Age; male/female Type 1/Type 2; duration Method of administration	Measurement properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
Audit of Diabetes-Dependent Quality of Life/ADDQoL							
Bradley, Todd et al. (1999) UK	1) Cambridge – outpatients (52) Mean 52.4 yrs; 54% M, 46% F T1 & T2; duration 12.7 yrs Self-completed questionnaire 2) Bromley – patients attending education open day (102) 61.7 yrs; 54% M, 46% F IDDM & NIDDM; duration 7.3 yrs Self-completed questionnaire	Internal consistency ✓	Content ✓ Construct ✓		✓	✓	
Woodcock et al. (2001) UK	GP patients (184) [131/71% responded] Range: 30-70 yrs (most 55-64 yrs) T2 Mailed questionnaire		Construct ✓			✓	
Bradley & Speight (2002) UK	Outpatients attending annual review at hospital clinic (795) T1 & T2 Self-completed questionnaire	Internal consistency ✓	Content ✓ Construct ✓		✓	✓	
DAFNE study group (2002) UK	RCT participants (169) Mean 40 yrs; 44% M, 56% F Moderate-to-poorly controlled T1; duration 16.6 yrs Questionnaire battery (ADDQoL, DTSQ, WBQ) at baseline, 6 mths & 1 yr			✓		✓	
Wee, Tan et al. (2006) Singapore	English-speaking Chinese, Indian, Malay patients—tertiary acute care referral hospital (173) mean age: 52 yrs; range: 18-80 yrs 55% M, 45% F duration of diabetes: mean 10 yrs, range 0-62	Internal consistency ✓	Content ✓ Construct ✓		✓	✓	

c) Diabetes 39/D-39

Reliability

Despite the authors' intention of enabling patients to express their individual experience of diabetes and its impact on their lives, it is not clear whether patients were involved in item derivation for the D-39 (Boyer and Earp, 1997).

Instrument development was in two phases. In the first, information derived from a literature review, existing quality of life instruments, and unstructured interviews with diabetes patients and health professionals (physicians, diabetes educators, pharmacists) was used to develop 93 items considered to address important aspects of patients' lives. Each item asked the respondent to assess the extent to which their quality of life was affected during the previous month by the action or activity within the item.

Following the application of factor analysis and item analysis, the instrument was reduced to 42 items in six domains. Item standard deviations were found to be approximately equal within each scale. With the exception of two items, larger correlations were found between items and scale scores than with the remaining scales. Item-total correlations were in the range 0.50-0.84.

In the second phase of the study, confirmatory factor analysis was used to confirm the presence of the six domains previously identified. Items were assessed for equivalent variances and item-total correlation. Item-total correlations were in the range 0.45-0.84. The instrument was reduced to 39 items and five domains.

The six domains from the first phase (Cary sample) produced Cronbach's alpha coefficients in the range 0.81-0.92. The final five-domain instrument produced alpha coefficients in the range 0.82-0.93 and 0.81-0.93 for the patients recruited from the community (Iowa) and from the hospital outpatient department (North Carolina), respectively. Estimates of internal consistency were all above the criterion of 0.70 for sub-groups of older patients and patients with no high school education.

Validity

In the first phase of instrument development, D-39 scores were correlated with global ratings of quality of life. There were no a priori hypotheses. Not all the results were significant but they were all in the anticipated direction. Four of the six dimension scores were significantly related to self-ratings of diabetes severity. Patients with seven or more concomitant conditions had the poorest scale scores (data not shown). Patients with no concomitant conditions had the best scores on five of the six dimensions (data not shown). Patients reporting depression as a concomitant condition had poorer scores on each of the six scales (data not shown).

Compared to younger patients, those aged over 75 had significantly poorer scores on the scales of energy and mobility. Younger patients had poorer scores, although not always significant, on the scales of diabetes control, anxiety and worry, social and peer burden, and diabetes medication (data not shown). Women had significantly poorer scores for the scales of energy and mobility, diabetes control, and anxiety and worry (data not shown). Patients who were not married had significantly poorer

scores for the scales of energy and mobility, and anxiety and worry, and significantly better scores on the sexual functioning scale.

In the second phase, the D-39 scores were compared with those for the eight scales of the SF-36. The instrument was assessed in both the community and the outpatient groups. As hypothesized, the largest correlations were found between the D-39 dimension of energy and mobility, and the SF-36 scale of physical functioning ($r = 0.71$), between the D-39 dimension of anxiety and worry, and the SF-36 scale of mental health ($r = 0.64$), and between the D-39 dimension of social burden and the SF-36 scale of social functioning ($r = 0.48$). Most correlations were statistically significant. All five dimensions of the D-39 had significant correlations with the self-reported global quality of life ($r = 0.21-0.44$) and self-reported diabetes severity ($r = 0.15-0.56$).

Relative to patients with no co-morbidity, patients with co morbid conditions had significantly poorer scores on the D-39 energy and mobility dimensions. Compared to younger patients, those aged over 75 had poorer scores on the scales of energy and mobility. Although not always statistically significant, younger patients had poorer scores on the scales of diabetes control, anxiety and worry, social and peer burden, and diabetes medication. With the exception of sexual functioning, in which men had significantly poorer scores, there were no significant score differences between men and women. Finally, compared to patients with no employment-limiting disabilities, those with employment-limiting disabilities had poorer scores across all five dimensions.

Compared to NIDDM patients, IDDM patients had significantly poorer scores for the D-39 dimensions of diabetes control, and anxiety and worry. These results had the greatest levels of statistical significance in the sample of patients recruited from the community. Patients using a combination of insulin and oral therapies had poorer scores across the five dimensions.

In a more limited study, involving low income respondents with diabetes in North Carolina, Camacho and colleagues (2002) found some additional evidence relevant to validation of D-39, with poorer subscale scores being associated with self-reported leg and foot complaints and a longer duration of diabetes.

Precision

The authors suggest that further research is needed to simplify the scoring system of the D-39 which may be unnecessarily precise.

Responsiveness

The instrument has not been assessed for responsiveness.

Acceptability

Of the 1000 questionnaires mailed to the Cary sample, 542 were returned (54.2%). There was a 73.3% response rate from the community pharmacy sample and a 45.8% response rate from the outpatient sample (see Table 6.11). Of the questionnaires returned, 70.8% and 41.4% were deemed usable from the community and outpatient samples, respectively. This suggests the questionnaire in its present form has poor acceptability.

Table 6.11 Developmental and evaluation studies relating to the Diabetes-39 instrument

Study Reference Country	Population, setting (n) Age; male/female Type 1/Type 2; duration Method of administration	Measurement properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
Diabetes 39/D-39							
Boyer & Earp (1997) USA	<p>Suburban Cary NC, pharmacist-run regional diabetes centre: 1000 selected from mailing list - 516 'usable' returned Age 52; M 240 (45.5%), F 288 (54.5%) T1 32.5%, T2 67.5%; duration 14 yrs White 88%</p> <p>Rural Iowa, GP patients (165) Age 62; M 74 (45%), F 90 (55%) T1 20%, T2 81%; duration 11.5 yrs White 100%</p> <p>Ethnically diverse Chapel Hill, NC (262) Age 55; M 93 (36%), F 169 (65%) T1 10%, T2 90%; duration 10 yrs White 42%, Black 54%</p> <p>Mailed questionnaire</p>	Internal consistency ✓	Construct ✓ Criterion ✓		✓	✓	
Camacho et al. (2002) USA	<p>Ethnically diverse (249) Age 54.4, range 18-87 M 77, F 172 T1 16%, T2 84%; mean duration 7.8, range 0-60 Insulin 32% yes, 68% no Mode of administration unclear</p>		Construct ✓				

d) Diabetes Health Profile/DHP

Reliability

The content of the DHP was derived following a literature review, a review of available instruments, interviews with 25 IDDM and insulin-requiring patients and discussions with diabetes health-care professionals (Meadows et al., 1996). The interviews were analysed on the basis of thematic content which generated 95 items. Four assessors independently grouped the items into five areas. All four allocated 81% of the items to the same five areas; the remainder were allocated following discussion. No additional content was suggested but some items were re-worded.

Following a survey of patients, 24 items with poor levels of endorsement and low or high levels of intercorrelation were removed from the instrument. The structure of the instrument was assessed in three samples of patients using principal axis factoring (PAF). The first PAF analysis showed that there were two additional factors to those hypothesized. The 16 items loading onto these factors were removed, together with 12 items with low factor loadings. The level of correspondence between composition of the three resultant factors, and item grouping carried out by the assessors was found to be moderate but satisfactory.

After application of a forced three-factor PAF analysis on the remaining 43 items, a further 11 items were removed that had either low factor loadings or high loadings on more than one factor. The remaining 32 items contributed to three dimensions labelled psychological distress (PD; 14 items), barriers to activity (BA; 13 items) and disinhibited eating (DE; 5 items). Item-total correlations were in the range 0.47-0.75 and all items had higher item-total correlations within their own dimensions than with the other dimensions. The PAF results were confirmed across sexes and age-groups, and when the sample was randomly split in two to form two separate sub-samples. One final sample of patients confirmed the factor structure of the 32-item DHP in this evaluation.

Cronbach's alphas for two of the samples in which the instrument was developed were: PD (0.85-0.86), BA (0.82-0.85), and DE (0.77-0.80) (Meadows et al., 1996). Test-retest reliability has not been reported by the developers, although Whitty et al., (1997) tested the PD and BA dimensions, along with the other test items used, by administering the instrument twice, three weeks apart, to a sample of patients with NIDDM. 95% confidence intervals for the intraclass correlation coefficients were 0.90-0.96.

The DHP-1 has been adapted for use with Type 2 diabetics following studies with UK and Danish samples (Meadows et al., 2000). The instrument has the same three subscales comprising 18 items, irrelevant content (e.g. items relating to insulin therapy) having been removed. Cronbach's alpha for the modified scale (DHP-18) ranged 0.70-0.88, and all item-scale correlations exceeded 0.40.

Validity

Face and content

The authors state that the methods of item derivation and dimension development are evidence of satisfactory face and content validity for the DHP (Meadows et al., 1996). However, they acknowledge that a number of important areas, such as lack of social

support, fear/worry about late complications, and satisfaction with treatment and care providers, are absent (Meadows et al., 2000). It is suggested the DHP be used in combination with other disease-specific measures such as the DTSQ and PAID, as well as generic measures when appropriate, in order to obtain a full picture of the patient's level of functioning (Meadows et al., 2000).

Convergent

DHP scores were compared with those for the Hospital Anxiety and Depression Scale/HADS and the SF-36. Correlations were in the range 0.17-0.68 and all were statistically significant. As hypothesized, the highest correlations were found between the PD and BA dimensions and the HADS and the SF-36.

Discriminant

The authors also hypothesized that women would score higher than men on the PD and DE dimensions. These predictions were in part supported in one of the initial study samples, with women under 40 scoring significantly higher than men on the PD dimension, and women aged 65 years and under scoring significantly higher than men on the DE dimension. In another smaller sample, the PD dimension did not significantly differ between women and men, but women had a significantly higher mean score on the DE dimension. In the study to develop the DHP-18 (Meadows et al., 2000), it was hypothesized that insulin-treated patients would have higher PD and BA scores due to the increased demands of their treatment. This proved to be the case for the BA subscale where there were significant differences; however, for the PD subscale, it was true only in the UK sample.

Responsiveness

The DHP-1 has not been formally assessed for responsiveness. However, the PD and BA dimensions within the earlier version of the DHP have been assessed for responsiveness (Whitty et al., 1997). Following a literature review and discussions with clinicians, it was hypothesized that changing NIDDM patients to insulin treatment should result in improvements in psychological distress and energy. The PD and BA dimensions produced standardised response means (SRM) of 0.23 and 0.02 at six weeks follow-up, compared to an SRM of 0.85 for the Newcastle Diabetes Symptoms Questionnaire/NDSQ (McColl et al., 1995). Smaller SRMs were found at three months follow-up.

Precision

In the initial studies (Meadows et al., 1996), all three dimensions showed a positive skew (less dysfunctioning) and less than six percent of patients scored at the floor or ceiling on any dimension. Floor effects (a high percentage of patients scoring at the lowest level of dysfunction) were found for both language versions of the DHP-18 (Meadows et al., 2000), particularly in respect of the PD scale in the diet-treated group. The percentage of patients obtaining the maximum score (ceiling effect) on the three subscales was acceptable, however.

Acceptability

Two of the samples recruited for the development of the DHP-1 produced response rates of 79.0-86.0%. Anonymity meant that the response rate could not be calculated for one of the samples (Meadows et al., 1996). In the larger sample of 2239 patients, all 43 items were answered by 84.85% of the sample, with a significant association

between lower completion rate and increasing age. There was a response rate of 81.8% for the UK arm of the development study for the DHP-18

Feasibility

No specific evidence was found.

Table 6.12 Developmental and evaluation studies relating to the Diabetes Health Profile

Study Reference Country	Population & setting (n) Age; male/female Type 1/Type 2; duration Method of administration	Measurement properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
Diabetes Health Profile/DHP							
Meadows et al. (1996) UK	Insulin-dependent or insulin-requiring outpatients All ID/IR at one clinic (278) Mean age 41, range 20-65 Duration 13.7 yrs Mailed out questionnaire Outpatients 54 hospitals England & Wales (2239) Age 39.8, range 16-84 M 51%, F 49% Duration 13.1 yrs Questionnaire completed during waiting time, or returned by post 7 hospitals NE England (295) Age 51.5 range 19-90 M 52%, F 48% Mailed out questionnaire	Internal consistency ✓	Convergent ✓ Construct ✓		✓	✓	
Whitty et al. (1997) UK	Prospective follow-up of patients (48) commencing insulin at six diabetic clinics NE England Age: 54% <60, 46% >60 M 42%, F 58% T2; mean duration 7 yrs, range 1-17 yrs Self-complete items from SF-36, HADS, NDSQ, DHP, at baseline, 6 wks, 3 mths	Test-retest ✓		✓			
Meadows et al. (2000) UK	Consecutive patients (650), 175 insulin-treated, Age 57, M/F 50/50; 69 diet-treated Age 65; M 62%, F 38% 182 tablet-treated Age 64; M 59%, F 41% Mailed out questionnaire	Internal consistency ✓	Construct ✓		✓	✓	

e) Diabetes Quality-of-Life Measure/DQOL

Reliability

The development and initial validation of the DQoL was carried out by the Diabetes Control and Complications (DCCT) Research Group. The content of the DQoL was derived from the following three sources: a literature review identifying the concerns of diabetic patients and problems that impact on their lives, consultation with clinicians knowledgeable about diabetes, and patients with IDDM. The meaning, relevance and readability of the instrument were assessed during its development by giving draft versions to IDDM patients; drafts were also reviewed by health professionals. The initial item pool comprised items considered to be of greatest relevance to patients with IDDM undergoing treatments of differing intensity.

In the original reporting of the instrument, the DCCT Research Group (1988) reported Cronbach's alpha coefficients ranging from 0.69 to 0.92 for the scales of diabetes-related worry and total scores, respectively. Only the former dimension fell below 0.70. Parkerson et al., (1993) reported alpha values in the range 0.52-0.88 for the diabetes worry and total DQOL scores, respectively. Jacobson et al. (1994) reported alpha values in the range 0.47-0.87 for patients with IDDM and NIDDM. With the exception of the diabetes worry scale ($r = 0.47-0.49$), the reliability estimates were regarded as similar to those reported in previous studies.

Test-retest reliability was assessed by asking patients to complete a second questionnaire at a mean of nine days after it was first administered. Pearson correlations were in the range 0.78-0.92 for the social/vocational worry and total scores, respectively (DCCT Research Group, 1988).

Validity

The DQOL items were derived from IDDM patients and clinicians, together with the literature on psychosocial aspects of diabetes. Selected patients, as well as clinicians, then reviewed the items for content relevance. On the basis of patient input, the instrument was expanded to include worries about the future (DCCT Research Group, 1988). In this original evaluation, the DQOL was compared with three instruments: the Symptom Checklist-90-R/SCL, the Bradburn Affect Balance Scale/ABS, and the Psychosocial Adjustment to Illness Scale/PAIS. Several hypotheses were constructed. First, the DQOL worry scales would have larger correlations with the SCL total score than the PAIS and ABS. Second, the DQOL worry scales would have similar levels of correlation with the ABS and PAIS. Third, the DQOL satisfaction scale would have the largest correlation with the ABS. Fourth, the DQOL impact scale would have the largest correlation with the PAIS scales, with the exception of the PAIS distress scale. Finally, the DQOL total scores would have significant correlations with all instrument scores and the DQOL scales would have positive correlations with all instrument scores. Correlations were expected to fall within the range 0.3-0.7, indicating that constructs were similar but not identical.

The two DQOL worry scales were significantly correlated with the SCL total score ($r = 0.40-0.50$) and these were stronger than all correlations with the PAIS and ABS except for the PAIS scale of psychological distress ($r = 0.46$). The DQOL worry scales had similar low levels of correlation with the ABS and the PAIS except for the aforementioned psychological distress scale of the PAIS. The DQOL satisfaction

scale had a significant correlation ($r = -0.55$) with the ABS but had a slightly larger correlation with the PAIS scale of health-care orientation. The DQOL impact scale did produce the largest correlations with the PAIS scales although the PAIS psychological distress scale correlated more highly with the DQOL impact scale than expected. Finally, the DQOL total scores did have significant correlations with all the instrument scores and all correlations were positive.

The DCCT study found two small but significant associations with sex: women reported DQOL scores reflecting a greater impact of diabetes and greater diabetes-related worries. Two studies have compared the DQOL with generic instruments. The first compared the DQOL with the Duke-UNC Health Profile/DUHP, the General Health Perceptions Profile/GHP, and the Health and Daily Living Form/HDL (Parkerson et al., 1993). There were no formal hypotheses but the authors expected DQOL scores to explain greater variance in disease indicators than scores for the generic instruments. Of the disease indicators (duration of diabetes, complications and intensity of treatment), only the complications variable was a statistically significant predictor.

The DQOL total scores had 28% of variation explained by four co-morbidity and psychosocial variables. The DQOL social/vocational worry dimension had the most variance explained (41%) by these variables. The impact dimension had the least variance explained (12%). Similar analyses of a modified DQOL that separated the instrument into generic and disease-specific components found that more variance was explained by the generic component. Neither of the modified scales had a statistically significant relationship with the diabetes-related variables.

In a stepwise regression analysis, sex and age did not enter the equation when DQOL total scores and satisfaction, impact and diabetes worry scales were the dependent variables. However, age did enter the equation when social/vocational worry was the dependent variable. Age was predictive of less social worry. Marriage entered the equation when the two DQOL worry dimensions were dependent variables: being married was predictive of less worry and better mental health.

The second study compared the DQOL with the SF-36 scales of physical functioning, social functioning, role limitations due to physical problems, pain, and general health perception (Jacobson et al., 1994). The total DQOL had small to moderate levels of correlation with the SF-36 scales ($r = 0.33-0.60$). The DQOL scales of satisfaction and impact had the largest correlations with the SF-36 scales, ranging 0.28-0.50 and 0.30-0.59, respectively.

This study also assessed the relationship between the DQOL and complications using regression analysis, after adjusting for sociodemographic factors. The DQOL impact and satisfaction scales, and total scores had a significant relationship with the number of complications among patients with IDDM. The DQOL total scores, and impact, satisfaction and diabetes worry scales had a significant relationship with the severity of diabetes among patients with IDDM. The DQOL satisfaction scale had a significant relationship with the number of complications in patients with NIDDM. The DQOL impact and satisfaction scales, and total scores had a significant relationship with the severity of diabetes among patients with NIDDM. DQOL total scores were significantly correlated with age. Separated or divorced patients were

found to experience worse quality of life than their counterparts, but data were not presented.

Lloyd and colleagues (1992) followed up in adulthood a sample who had been first identified as IDDM in childhood. Patients with specific complications (macrovascular disease or nephropathy) had significantly poorer scores for DQOL and also there was deteriorating DQOL scores with each additional complication.

A study comparing younger with older patients with diabetes, found that older age and type 1 diabetes were independently associated with more favourable scores on DQOL (Trief et al., 2003).

In an application of the instrument to a sample of young adults with Type 1 diabetes in England, the instrument was found to have a different factor structure with three scales emerging, namely, social relationships, diabetes concerns, and impact (Eiser et al., 1992). Apart from a correlation with poor attendance at the study clinic, there were few significant correlations between scales of DQOL and clinical or disease-related variables.

Responsiveness

The responsiveness of the DQOL has not been formally assessed but the instrument's authors cite two studies as evidence for the responsiveness of the instruments. In the first, patients with end-stage renal disease were given either a kidney transplant or a combined pancreas/kidney transplant. 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 receiving the kidney transplant alone (Nathan et al., 1991). The second study compared the quality of life of patients who received an implantable pump with those receiving normal insulin treatments (Selam et al., 1992). The DQOL scale of satisfaction showed an improvement but there were no other changes. More recently, a small scale study appeared (Weinger and Jacobson, 2001) in which patients with diabetes attending a clinic intended to provide intensive treatment to improve control were assessed longitudinally on a number of measures. Patients showing improved glycaemic control also exhibited small but significant changes in scales of DQOL.

Precision

No specific evidence was found.

Acceptability

Information relating to the acceptability of the DQOL is available only for the two studies reporting comparisons with generic instruments. In the first, 131 out of 179 IDDM patients completed the DQOL and there were no missing items (Parkerson et al., 1993). The analysis was limited to those patients completing the DQOL. There were no significant differences between responders and non-responders to the DQOL for any of the demographic, psychosocial, or co morbidity variables collected. There were also no significant differences for disease duration and complications. However, a significant difference was found for intensity of treatment and 79.5% of non-responders were insulin-pump patients. The second study reported that 88% of patients agreed to participate (Jacobson et al., 1994). There were differences in responses to DQOL subscales, reflecting the fact that the social/vocational worry

subscale is less suitable for older NIDDM patients. The responses were different for the subscales of satisfaction (n = 228), diabetes worries (n = 219), impact (n = 217), and social/vocational worries (n = 61).

Feasibility

No specific evidence was found.

Table 6.13 Developmental and evaluation studies relating to the Diabetes Quality of Life Measure/DQOL

Study Reference Country	Population (n) Age Method of administration Setting	Measurement properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
DCCT Research Group (1988) USA	Outpatients (192) Age 28 (adults) & 16 (adolescents) IDDM in adults and adolescents Administered during clinic visit	Internal consistency ✓ Reproducibility ✓	Construct ✓				
DCCT Research Group (1996) USA	Outpatients (1441) Age 27 IDDM Administered during clinic visit			✓			
Eiser et al. (1992) UK	Outpatients (69) Age: 21 Type 1 diabetes Self-completed in clinic		Construct ✓				
Jacobson et al. (1994) USA	Boston (240) Age: (Type 1) 44 Age (Type 2) 60 Self-completed during clinic visit	Internal consistency ✓	Construct ✓				
Lloyd et al. (1992) USA	Pittsburgh hospital register follow-up (175) Age: >28 Childhood IDDM Postal questionnaire		Construct ✓				
Nathan et al. (1991) USA	Recipients of transplant surgery at Boston hospital (33) Age: 34 IDDM Self-completed questionnaire			✓			

Study Reference Country	Population (n) Age Method of administration Setting	Measurement properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
Parkerson et al. (1993) USA	8 clinics (170) Age: 34 IDDM Self-completed during clinic visit	Internal consistency ✓	Construct ✓				
Selam et al. (1992) USA	Multi-centre trial (56) IDDM			✓			
Trief et al. (2003) USA	Specialist diabetes centre, Syracuse (191) Age: (younger group) 47 (older group) 71		Construct ✓				
Weinger and Jacobson (2001) USA	Specialist clinic in Boston (55) Age: 34 Completed during clinic visit			✓			

f) Diabetes Quality of Life Clinical Trial Questionnaire/DQLCTQ

Reliability

To develop the DQLCTQ, patient focus groups (30 patients) and expert clinician panels (11 clinicians) in the USA and France identified domains of importance. The literature was then reviewed to find generic and disease-specific instruments containing these domains. The major components of the draft instrument were based on these findings, and data were extracted from validated generic and disease-specific instruments. Generic instruments used were the SF-20 and SF-36; specific measures were the Diabetes Quality of Life Measure/DQOL (DCCT Group, 1988), the Questionnaire on Stress in Diabetes (Waadt et al., 1992) and the Hypoglycaemia Fear Survey/HFS (Cox et al., 1987). Instruments dealing with social stigma, treatment satisfaction, and symptoms were not available; these items were therefore developed. This process produced 293 items that were assessed for face and content validity by a group of researchers expert in the measurement of health-related quality of life.

The draft instrument was evaluated in patients attending five internal medicine practices and diabetes care centres in the USA. Following this study, and using the results of the focus groups and clinician panels, the instrument was reduced to make it acceptable for multinational clinical trials. Redundant items and domains were removed and domains with poor psychometric properties were modified or removed. Two domains were created for insulin-specific comparisons, treatment satisfaction and treatment flexibility.

Cronbach's alpha coefficients for the DQLCTQ domains were greater than 0.70, with the exception of the DQOL dimensions of social worry (0.62) and the DQOL diabetes worry (0.53) – i.e. these domains did not reach the levels of reliability required for group comparisons. The newly developed domains produced alpha coefficients ranging from 0.77 to 0.89 for the frequency of symptoms and treatment flexibility domains, respectively.

Test-retest reliability was assessed 7-10 days after baseline among the initial pilot sample of patients. Intraclass correlation coefficients were in the range 0.49-0.90 for the social stigma and health distress dimensions, respectively. The diabetes worry and the social stigma dimensions produced coefficients below 0.70. Revisions to the instrument meant that the test-retest reliability was not reported for the newly created domains of treatment satisfaction, treatment flexibility, frequency of symptoms, or bothersomeness of symptoms. The revised version of the instrument, the DQLCTQ-R, has good levels of reliability with alpha and test-retest coefficients all above 0.70 (Shen et al., 1999).

Validity

The draft instrument was assessed for face and content validity by a group of researchers with expertise in the measurement of health-related quality of life. The DQLCTQ was further assessed for validity through comparisons with clinical and sociodemographic variables. On the whole, the hypotheses were supported by the data. Patients with good metabolic control had significantly higher mean DQLCTQ scores than those with poor metabolic control. Patients who considered themselves to be in good control of their diabetes had significantly higher mean DQLCTQ scores than those who felt they were in poor control. With the exception of the domains of

social worry (DQOL), worry (HFS), treatment satisfaction, and treatment flexibility, patients with IDDM had higher mean DQLCTQ scores than those with NIDDM. With the exception of the dimensions of satisfaction, impact, and social worry and social stigma, women patients had poorer mean DQLCTQ scores than men.

Responsiveness

The responsiveness of the DQLCTQ was assessed by mean changes in DQLCTQ scores for patients whose metabolic control had improved or worsened over six months. For the improved group, the satisfaction (DQOL) and treatment satisfaction scales produced significantly better scores compared to baseline. For the worsened group, the mental health scale produced a significantly worse score compared to baseline. The DQLCTQ-R scales of treatment satisfaction, health/distress, mental health, and DQOL satisfaction produced significantly better scores compared to baseline for the improved group.

Acceptability

Less than 10% of items were missing for 83% of questionnaires administered (Kotsanos et al., 1997).

Feasibility

The authors report that the revised DQLCTQ can easily be administered and completed in ten minutes. From an examination of the questionnaire, this would appear somewhat optimistic.

Table 6.14 Developmental and evaluation studies relating to the Diabetes Quality of Life Clinical Trial Questionnaire/DQLCTQ

Study Reference Country	Population & setting (n) Age; male/female Type 1/Type 2; duration Method of administration	Measurement properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
Diabetes Quality of Life Clinical Trial Questionnaire/DQLCTQ							
Kotsanos et al. (1997) Shen et al. (1999) Canada USA France Germany	Pilot study USA (123) Multinational randomised open-label crossover trial (T1 468, T2 474) T1 age 33.8; duration 12.6 M 56%, F 44% White 97% T2 age 58.2; duration 12.5 Questionnaire administered during clinic visit	Internal consistency ✓ Test-retest ✓	Face & content ✓ Construct ✓ Discriminant ✓ Criterion ✓	✓		✓	✓

Other diabetes-specific instruments identified from the review

Table 6.15 Overview of newly developed diabetes-specific instruments or single study reporting of measurement properties and/or evaluation.

Instrument Reference	Population, setting (n)	Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility	Summary; comments
Country	Age; male/female							No other records identified unless stated
	Type 1/Type 2; duration							
	Method of administration							
Diabetes Impact Measurement Scales/DIMS (Hammond and Aoki 1992) USA	Diabetes clinic patients (130) Mean: 45 yrs, range: 18-78 yrs; 42% M, 58% F Type 1 & 2, mean 11 yrs Self-administered questionnaire	Internal consistency ✓ Test-retest ✓	Construct ✓		✓	✓	✓	Designed to measure therapeutic impact in CTs Based on literature review, Rand instruments, SIP, AIMS, discussion with clinicians. 44 Likert-scale items in four subscales: symptoms (5 specific, 11 non-specific), 10 general well-being, 10 diabetes-related morale, 5 social role. Scores summed to produce 0-10 overall score. 15-20 mins completion time. No patient input. Correlated with VAS scales, clinical & demographic variables. Not all correlations >0.70. Some missing values. Test-retest not standard interval. No evidence for responsiveness.
Bournemouth Impact of Diabetes Scale (Everett, Kerr, 2005) UK	Diabetes clinic (237) Age: 37 Type 1 diabetes	Internal consistency ✓	Construct ✓					25 questions with responses on range 1-10. Is described as taking 5 minutes to complete. Good internal consistency and obtained significant differences between analogue and soluble forms of insulin. However no evidence of responsiveness. No other evidence for this recently reported instrument.
<i>Three related measures - unnamed</i> (Brod et al., 2006) USA	Web-based survey of individuals with diabetes (418)		✓					Three scales developed from focus groups and web-based survey: satisfaction (21 items), symptoms (30 items), and productivity (14 items). Validation included distinguishing type of medication, age. No other studies and no evidence of responsiveness.

DISCUSSION AND RECOMMENDATIONS

Generic measures

Five generic measures were considered in detail because of the availability of potentially supportive evidence: SF-36 (and its variant SF-12), SIP, HUI, QWB, EQ-5D. By far the most substantial evidence was available in relation to SF-36. It has been widely used to capture the health status consequences of diabetes, in a wide range of settings and populations. It provides important evidence of the personal impact of the disorder. It has been extensively validated in the context of cross-sectional applications in diabetes. There is a small body of evidence also to support its use longitudinally to capture changes over time in health status and health-related quality of life. Most of this small body of evidence does suggest that the SF-36 is sensitive to change over time in important experiences for individuals with diabetes, although one small trial did fail to detect changes over time where other clinical evidence led investigators to expect change (Hill-Briggs et al., 2005). Responsiveness is always a critical requirement of patient-reported outcome measures. It becomes a particularly important issue in the context of diabetes where there is debate about whether interventions to achieve tight control of diabetes may have adverse effects on quality of life and such adverse effects need to be distinguished from consequences of the illness.

There is encouraging evidence for the use of instruments such as HUI and EQ-5D, instruments that may be important where assessment of utilities is needed. Even less evidence was found to address responsiveness of these types of instrument in diabetes than was found for non-utility generic instruments.

Diabetes-specific measures

In terms of volume of discussion, it is clear that patient-reported health instruments have an important role in improving understanding of diabetes and interventions for diabetes. However, given the clear importance of patients' experience and health-related quality of life in the condition, it is remarkable how few well-conducted studies were found independently to examine the measurement properties and practical usefulness of patient-reported health instruments. Even less common were studies directly comparing the performance of alternative instruments within samples of individuals with diabetes.

Three instruments have some evidence of measurement properties that might make them appropriate for further evaluation in the context of the NHS: ADDQOL, DHP and DQOL. They appear reasonably short for routine, regular use with adequate response rates and have some supportive evidence of measurement properties. Importantly, there is some evidence of responsiveness for each of the three instruments, although in no case was formal rigorous evidence of responsiveness found. Additional limitations include the limited coverage of the domains of the DHP, and evidence that the originally intended scales of DQOL may not be stable and may not pertain when completed by individuals with diabetes in the UK.

Recommendations

For assessment of broader aspects of health status in diabetes, the SF-36 clearly provides reliable insights; substantial evidence exists to support its use in diabetes and more from a wide range of other applications. Where, specifically, utility values are

required, there is also evidence to support use of EQ-5D and HUI. Normally it is recommended that a disease-specific measure is used in conjunction with a generic measure to assess particular problems of any given long-term condition. There is insufficient evidence strongly to single out any particular disease-specific instrument in diabetes. Of the large number of such instruments, ADDQOL, DHP and DQOL may warrant more attention to establish the case for a disease-specific instrument.

REFERENCES

- Ahroni JH, Boyko EJ. Responsiveness of the SF-36 among veterans with diabetes mellitus. *Journal of Diabetes and its Complications* 2000;**14**:31-9.
- Aikens JE, Bingham R, Piette JD. Patient-provider communication and self-care behavior among type 2 diabetes patients. *Diabetes Educator* 2005;**31**:681-90.
- Alonso J, Ferrer M, Gandek B, Ware JE Jr, Aaronson NK, Mosconi P *et al.* Health-related quality of life associated with chronic conditions in eight countries: results from the International Quality of Life Assessment (IQOLA) Project. *Quality of Life Research* 2004;**13**:283-98.
- Anderson JP, Kaplan RM, Berry CC, Bush JW, Rumbaut RG. Interday reliability of function assessment for a health status measure: the Quality of Well-Being scale. *Medical Care* 1989;**27**:1076-84.
- Anderson RM, Fitzgerald JT, Wisdom K, Davis WK, Hiss RG. A comparison of global versus disease-specific quality-of-life measures in patients with NIDDM. *Diabetes Care* 1997;**20**:299-305.
- Bardsley MJ, Astell S, McCallum A, Home PD. The performance of three measures of health status in an outpatient diabetes population. *Diabetic Medicine* 1993;**10**:619-26.
- Bayliss EA, Bayliss MS, Ware JE Jr, Steiner JF. Predicting declines in physical function in persons with multiple chronic medical conditions: what we can learn from the medical problem list. *Health and Quality of Life Outcomes*. 2004;**2**:47.
- Bharmal M, Thomas J. Comparing the EQ-5D and the SF-6D descriptive systems to assess their ceiling effects in the US general population. *Value in Health* 2006;**9**:262.
- Bowker SL, Pohar SL, Johnson JA. A cross-sectional study of health-related quality of life deficits in individuals with co-morbid diabetes and cancer. *Health and Quality of Life Outcomes* 2006;**4**.
- Boyer JG, Earp JA. The development of an instrument for assessing the quality of life of people with diabetes: Diabetes-39. *Medical Care* 1997;**35**:440-53.
- Bradley C. Design of a renal-dependent individualised quality of life questionnaire. *Advances in Peritoneal Dialysis* 1997;**13**:116-20.
- Bradley C, Lewis KS. Measures of psychological well-being and treatment satisfaction developed from the responses of people with tablet-treated diabetes. *Diabetic Medicine* 1990;**7** :445-51.
- Bradley C, Todd C, Gorton T, Symonds E, Martin A, Plowright R. The development of an individualized questionnaire measure of perceived impact of diabetes on quality of life: the ADDQoL. *Quality of Life Research* 1999;**8**:79-91.
- Bradley C, Speight J. Patient perceptions of diabetes and diabetes therapy: assessing quality of life. *Diabetes and Metabolism Research and Reviews* 2002;**18**:S64-S69.

Brod M, Skovlund SE, Wittrup-Jensen KU. Measuring the impact of diabetes through patient report of treatment satisfaction, productivity and symptom experience. *Quality of Life Research* 2006; **15**:481-91.

Camacho F, Anderson RT, Bell RA, Goff DCJ, Duren-Winfield V, Doss DD *et al.* Investigating correlates of health related quality of life in a low-income sample of patients with diabetes. *Quality of Life Research* 2002;**11**:783-96.

Carey MP, Jorgensen RS, Weinstock RS, Sprafkin RP, Lantinga LJ, Carnrike CLJ *et al.* Reliability and validity of the Appraisal of Diabetes Scale. *Journal of Behavioral Medicine* 1991;**14**:43-51.

Chittleborough C, Baldock K, Taylor A, Phillips P. Health status assessed by the SF-36 along the diabetes continuum in an Australian population. *Quality of Life Research* 2006;**15**:687-94.

Clarke P, Gray A, Holman R. Estimating utility values for health states of Type 2 diabetic patients using the EQ-5D (UKPDS 62). *Medical Decision-Making* 2002;**22**:340-9.

Coffey JT, Brandle M, Zhou Hea. Valuing health-related quality of life in diabetes. *Diabetes Care* 2002;**25**:2238-43.

Cox D, Irvine A, Gonder-Frederick L, Nowacek G, Butterfield J. Fear of hypoglycemia: quantification, validation, and utilization. *Diabetes Care* 1987;**10**:617-21.

Cox DJ, Gonder-Fredrick L. Major developments in behavioral diabetes research. *Journal of Consulting and Clinical Psychology* 1992;**60**:628-38.

Currie CJ, McEwan P, Peters JR, Patel TC, Dixon S. The routine collation of health outcomes data from hospital treated subjects in the Health Outcomes Data Repository (HODaR): descriptive analysis from the first 20,000 subjects. *Value in Health* 2006;**8**:581-90.

DAFNE Study Group. Training in flexible, intensive insulin management to enable dietary freedom in people with type 1 diabetes: dose adjustment for normal eating (DAFNE) randomised controlled trial. *BMJ: British Medical Journal* 2002;**325**:746.

Davis WK, Hess GE, Hiss RG. Psychosocial correlates of survival in diabetes. *Diabetes Care* 1988;**11** :538-45.

Deaton C, Kimble LP, Veledar E, Hartigan P, Boden WE, O'Rourke R *et al.* The synergistic effect of heart disease and diabetes on self-management, symptoms, and health status. *Heart and Lung* 2006;**35**:315-23.

Diabetes Control and Complications Trial Research Group. Reliability and validity of a diabetes quality-of-life measure for the Diabetes Control and Complications Trial (DCCT). *Diabetes Care* 1988;**11**:725-32.

- Diabetes Control and Complications Trial Group. Influence of intensive diabetes treatment on quality-of-life outcomes in the Diabetes Control and Complications Trial. *Diabetes Care* 1996;**19**:195-203.
- Dunn SM, Smartt HH, Beeney LJ, Turtle JR. Measurement of emotional adjustment in diabetic patients: validity and reliability of ATT39. *Diabetes Care* 1986;**9**:480-9.
- Eiser C, Flynn M, Green E, Havermans T, Kirby R, Sandeman D *et al*. Quality of life in young adults with type 1 diabetes in relation to demographic and disease variables. *Diabetic Medicine* 1992;**9**:375-8.
- Elasz TA, Samuel-Hodge CD, DeVellis RF, Skelly AH, Ammerman AS, Keyserling TC. Development of a health status measure for older African-American women with type 2 diabetes. *Diabetes Care* 2000;**23**:325-9.
- Everett J, Kerr D. Measuring the impact of type 1 diabetes from the patient's perspective. *Journal of Diabetes Nursing* 2005;**9**:186-90.
- Fitzgerald JT, Davis WK, Connell CM, Hess GE, Funnell MM, Hiss RG. Development and validation of the Diabetes Care Profile. *Evaluation and the Health Professions* 1996;**19**:208-30.
- Fitzgerald JT, Anderson RM, Gruppen LD, Davis WK, Aman LC, Jacober SJ *et al*. The reliability of the Diabetes Care Profile for African Americans. *Evaluation and the Health Professions* 1998;**21**:52-65.
- Garratt AM, Schmidt LJ, Fitzpatrick R. Patient-assessed health outcome measures for diabetes: a structured review. *Diabetic Medicine* 2002;**19**:1-11.
- Glasgow RE, Ruggerio L, Eakin EG, Dryfoos J, Chobanian L. Quality of life and associated characteristics in a large national sample of adults with diabetes. *Diabetes Care* 1997;**20**:562-7.
- Griffiths R, Jayasuriya R, Maitland H. Development of a client-generated health outcome measure for community nursing. *Australian and New Zealand Journal of Public Health* 2000;**24**:529-35.
- Hammen C, Mayol A. Depression and cognitive characteristics of stressful life-event types. *Journal of Abnormal Psychology* 1982;**91**:165-74.
- Hammond GS, Aoki TT. Measurement of health status in diabetic patients: Diabetes Impact Measurement Scales. *Diabetes Care* 1992;**15**:469-77.
- Hartley LA. Functional health status of persons with diabetes in a nurse-managed clinic. *Diabetes Educator* 2002;**28**:106-14.
- Hendra TJ, Taylor CD. A randomised trial of insulin on well-being and carer strain in elderly type 2 diabetic subjects. *Diabetes Complications* 2004;**18**:148-54.
- Hermann BP, Vickrey BG, Hays RD, Cramer JA, Devinsky O, Meador K *et al*. A comparison of health-related quality of life in patients with epilepsy, diabetes and multiple sclerosis. *Epilepsy Research* 1996;**25**:113-8.

- Hill-Briggs F, Gary TL, Baptiste-Roberts K, Brancati FL. Thirty-Six-Item Short-Form outcomes following a randomized controlled trial in Type 2 diabetes. *Diabetes Care* 2005;**28**:444.
- Holmes J, McGill S, Kind P, Bottomley J, Gillam S, Murphy M. Health-related quality of life in Type 2 diabetes (T²ARDIS-2). *Value in Health* 2000;**3**:47.
- Hornquist JO, Wikby A, Hansson B, Andersson PO. Quality of Life: status and change (QLsc) reliability, validity and sensitivity of a generic assessment approach tailored for diabetes. *Quality of Life Research* 1993;**2**:263-79.
- Hornquist JO, Wikby A, Stenstrom U, Andersson PO. Change in quality of life along with type 1 diabetes. *Diabetes Research in Clinical Practice* 1995;**28**:63-72.
- Ingersoll GM, Marrero DG. A modified quality-of-life measure for youths: psychometric properties. *The Diabetes Educator* 1991;**17**:114-8.
- Jacobson AM, De Groot M, Samson JA. The evaluation of two measures of quality of life in patients with type I and type II diabetes. *Diabetes Care* 1994;**17**:267-74.
- Johnson JA, Maddigan SL. Performance of the RAND-12 and SF-12 summary scores in type 2 diabetes. *Quality of Life Research* 2004;**13**:449-56.
- Kotsanos JG, Vignati L, Huster W, Andrejasich C, Boggs MB, Jacobson AM *et al.* Health-related quality-of-life results from multinational clinical trials of insulin lispro. Assessing benefits of a new diabetes therapy. *Diabetes Care* 1997;**20**:948-58.
- Lee AJ, Morgan CL, Morrissey M, Wittrup-Jensen KU, Kennedy-Martin T, Currie CJ. Evaluation of the association between the EQ-5D (health-related utility) and body mass index (obesity) in hospital-treated people with Type 1 diabetes, Type 2 diabetes and with no diagnosed diabetes. *Diabetic Medicine* 2005;**22**:1482-6.
- Linzer M, Pierce C, Lincoln E, Miller DR, Payne SM, Clark JA *et al.* Preliminary validation of a patient-based self-assessment measure of severity of illness in type 2 diabetes: results from the pilot phase of the Veterans Health Study. *Journal of Ambulatory Care Management* 2005;**28**:167-76.
- Liu H, Hays RD, Adams JL, Chen WP, Tisnado D, Mangione CM *et al.* Imputation of SF-12 health scores for respondents with partially missing data. *Health Services Research* 2005;**40**:905-21.
- Lloyd C, Matthews KA, Wing RR, Orchard TJ. Psychosocial factors and complications of IDDM. The Pittsburgh Epidemiology of Diabetes Complications Study. VIII. *Diabetes Care* 1992;**15**:166-72.
- Lustman PJ, Anderson RJ, Freedland KE, De Groot M, Carney RM, Clouse RE. Depression and poor glycemic control: a meta-analytic review of the literature. *Diabetes Care* 2000;**23**:934-42.
- Maddigan SL, Feeny DH, Johnson JA. A comparison of the Health Utilities Indices Mark 2 and Mark 3 in type 2 diabetes. *Medical Decision-Making* 2003;**23**:489-501.

Maddigan SL, Feeny DH, Johnson JA. Construct validity of the RAND-12 and Health Utilities Index Mark 2 and 3 in type 2 diabetes. *Quality of Life Research* 2004;**13**:435-48.

Maddigan SL, Feeny DH, Johnson JA. Health-related quality of life deficits associated with diabetes and co-morbidities in a Canadian National Population Health Survey. *Quality of Life Research* 2005;**14**:1311-20.

McColl E, Steen N, Meadows KA, Hutchinson A, Eccles MP, Hewison J *et al*. Developing outcome measures for ambulatory care: an application to asthma and diabetes. *Social Science and Medicine* 1995;**41**:1339-48.

McGee HM, O'Boyle CA, Hickey AM, O'Malley KM, Joyce CRB. Assessing the quality of life of the individual: the SEIQoL with a healthy and a gastroenterology unit population. *Psychological Medicine* 1991;**21**:749-59.

Meadows KA, Steen N, McColl E, Eccles MP, Shiels C, Hewison J *et al*. The Diabetes Health Profile (DHP), a new instrument for assessing the psychosocial profile of insulin requiring patients: development and psychometric evaluation. *Quality of Life Research* 1996;**5**:242-54.

Meadows KA, Abrams C, Sandbaek A. Adaptation of the Diabetes Health Profile (DHP-1) for use with patients with Type 2 diabetes mellitus: psychometric evaluation and cross-cultural comparison. *Diabetic Medicine* 2000;**17**:572-80.

Nathan DM, Fogel H, Norman D, Russell PS, Tolkoff-Rubin N, Delmonico FL *et al*. Long-term metabolic and quality of life results with pancreatic/renal transplantation in insulin-dependent diabetes mellitus. *Transplantation* 1991;**52**:85-91.

Parkerson GRJ, Connis RT, Broadhead WE, Patrick DL, Taylor TR, Tse CK. Disease-specific versus generic measurement of health-related quality of life in insulin-dependent diabetic patients. *Medical Care* 1993;**31**:629-39.

Peyrot M, Rubin RR. Validity and reliability of an instrument for assessing health-related quality of life and treatment preferences: the insulin delivery system rating questionnaire. *Diabetes Care* 2005;**28**:53-8.

Polonsky WH, Anderson BJ, Lohrer PA, Welch G, Jacobson AM, Aponte JE *et al*. Assessment of diabetes-related distress. *Diabetes Care* 1995;**18**:754-60.

Polonsky WH. Understanding and assessing diabetes-specific quality of life. *Diabetes Spectrum* 2000;**13**:36.

Roberts R, Hemingway H, Marmot M. Psychometric and clinical validity of the SF-36 general health survey in the Whitehall II study. *British Journal of Health Psychology* 1997;**2**:285-300.

Rosenthal MJ, Fajardo M, Gilmore S, Morley JE, Naliboff BD. Hospitalization and mortality of diabetes in older adults: a three-year prospective study. *Diabetes Care* 1998;**21**:231-5.

Schwartz CE, Genderson MW, Kaplan RM, Anderson JP, Holbrook T. Covariation of physical and mental symptoms across illnesses: results of a factor analytic study. *Annals of Behavioral Medicine* 1999;**21**:122-7.

Selam JL, Micossi P, Dunn FL, Nathan DM. Clinical trial of programmable implantable insulin pump for type I diabetes. *Diabetes Care* 1992;**15**:877-85.

Shen W, Kotsanos JG, Huster WJ, Mathias SD, Andrejasich CM, Patrick DL. Development and validation of the Diabetes Quality of Life Clinical Trial Questionnaire. *Medical Care* 1999;**37**:AS45-AS66.

Skovlund SE. Patient-reported assessments in diabetes care: clinical and research applications. *Current Diabetes Reports* 2005;**5**:115-23.

Smith DG, Domholdt E, Coleman KL, del Aguila MA, Boone DA. Ambulatory activity in men with diabetes: relationship between self-reported and real-world performance-based measures. *Journal of Rehabilitation Research and Development* 2004;**41**:571-9.

Smith DW. The population perspective on quality of life among Americans with diabetes. *Quality of Life Research* 2004;**13**:1391-400.

Speight J, Bradley C. ADDQol indicates negative impact of diabetes on quality of life despite high levels of satisfaction with treatment. *Diabetologia* 2000;**43**:A225 (Abstract 864).

Supina AL, Feeny DF, Carroll LJ, Johnson JA. Misinterpretation with norm-based scoring of health status in adults with type 1 diabetes. *Health and Quality of Life Outcomes* 2006;**4**.

Tabaei BP, Shill-Novak J, Brandle M, Burke R, Kaplan RM, Herman WH. Glycemia and the quality of well-being in patients with diabetes. *Quality of Life Research* 2004;**13**:1153-61.

Trief PM, Grant W, Elbert K, Weinstock RS. Family environment, glycemic control, and the psychosocial adaptation of adults with diabetes. *Diabetes Care* 1998;**21**:241-5.

Trief PM, Aquilino C, Paradies K, Weinstock RS. Impact of the work environment on glycemic control and adaptation to diabetes. *Diabetes Care* 1999;**22**:569-74.

Trief PM, Wade MJ, Pine D, Weinstock RS. A comparison of health-related quality of life of elderly and younger insulin-treated adults with diabetes. *Age and Ageing* 2003;**32**:613-8.

UK Prospective Diabetes Study Group. Quality of life in type 2 diabetic patients is affected by complications but not by intensive policies to improve blood glucose or blood pressure control (UKPDS 37). *Diabetes Care* 1999;**22**:1125-36.

- Van der Ven NCW, Weinger K, Yi J, Pouwer F, Ader H, Van der Ploeg HM *et al.* The Confidence in Diabetes Self-Care scale. Psychometric properties of a new measure of diabetes-specific self-efficacy in Dutch and US patients with type 1 diabetes. *Diabetes Care* 2003;**26**:713-8.
- Waadt S, Duran G, Waadt M, Herschbach P. Quality of life in people with type 2 diabetes mellitus. In Lefèbvre PJ, Stabdl E, eds. *New aspects in diabetes*, Berlin, Germany: Walter de Gruyter, 1992.
- Wee H-L, Tan C-E, Goh S-Y, Li S-C. Usefulness of the Audit of Diabetes-Dependent Quality-of-Life (ADDQoL) questionnaire in patients with diabetes in a multi-ethnic Asian country. *Pharmacoeconomics* 2006;**24**:673-82.
- Weinger K, Jacobson AM. Psychosocial and quality of life correlates of glycemic control during intensive treatment of type 1 diabetes. *Patient Education and Counseling* 2001;**42**:123-31.
- Wexler DJ, Grant RW, Wittenberg E, Bosch JL, Cagliero E, Delahanty L *et al.* Correlates of health-related quality of life in type 2 diabetes. *Diabetologia* 2006;**49**:1489-97.
- Whitty R, Steen N, Eccles MP, McColl E, Hewison J, Meadows KA *et al.* A new self-completion outcome measure for diabetes: is it responsive to change? *Quality of Life Research* 1997;**6**:407-13.
- Woodcock AJ, Julious SA, Kinmonth AL, Campbell MJ. Problems with the performance of the SF-36 among people with type 2 diabetes in general practice. *Quality of Life Research* 2001;**10**:661-70.
- Wu SY, Sainfort F, Tomar RH, Tollios JL, Fryback DG, Klein R *et al.* Development and application of a model to estimate the impact of type 1 diabetes on health-related quality of life. *Diabetes Care* 1998;**21**:725-31.