

Diabetes

Structured review

Instruments for Diabetes: a Review

National Centre for Health Outcomes Development, University of Oxford
Patient-reported Health Instruments Group (*formerly the Patient-Assessed Health Outcomes Programme*)
Report to the UK Department of Health July 2000

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Executive Summary

Background

This report presents a review of diabetes-specific measures of symptoms and health-related quality of life. There has been considerable research into the effects of diabetes on quality of life, yielding numerous instruments designed for use as health outcome measures. This review will provide users of such measures with information guiding the selection and evaluation of these instruments for future application, such as in clinical trials.

Research Aims

- to identify patient-reported health outcome measures specific to diabetes;
- to extract and assess the evidence relating to the development and evaluation of the instruments, and make recommendations as to their application.

Methods

Electronic databases from 1990-1999 were searched using keywords relevant to the development and testing of instruments specific to diabetes. Several other sources, including conference abstracts, were also searched. The names of instruments were then used in a second search strategy. Instrument authors were sent a letter requesting additional information relating to development, evaluation and scoring.

After receiving replies from authors and retrieving published papers, the following information was extracted relating to the development and evaluation of the instruments:

- the purpose of the instrument, including the underlying phenomena being measured and the proposed application;
- instrument development and scoring;
- patient samples in which the instrument was developed and tested;
- measurement properties of reliability, validity and responsiveness;
- response rates and missing data.

Key Findings

20 instruments met the inclusion criteria for the review. The majority were developed and evaluated in Europe or the United States. Two of the instruments, namely Quality of Life: Status and Change (Hornquist et al., 1993) and the Well-being Questionnaire (Bradley, 1994), are predominantly generic in focus but were included in the review because of their widespread use in patients with diabetes. All but four of the instruments have been evaluated in patients with both type I and type II diabetes.

The content of the instruments covers ten quality of life or symptom domains but was largely concentrated in the domains of diabetic symptoms, global health and quality of life, personal constructs, physical functioning, psychological well-being, social well-being, and treatment and quality of life.

Most of the disease-specific instruments have one published evaluation relating to the measurement properties of reliability and validity. Very few instruments have undergone a formal evaluation of responsiveness to change.

The Diabetes Quality of Life Measure (Jacobson, 1997) has the largest number of published evaluations, and has evidence for its reliability and validity across four nationalities of diabetic patients.

Three of the strictly disease-specific instruments have been developed and evaluated in the UK, namely the Audit of Diabetes Dependent Quality of Life (Bradley, Todd et al. 1999), the Diabetes Health Profile (Meadows, Steen et al., 1996), and the Newcastle Diabetes Symptom Questionnaire (McColl, Steen et al., 1995).

The disease-specific instruments developed in the UK have not been as extensively evaluated as the Diabetes Quality of Life Measure but have undergone a more rigorous approach to development. The evidence for the measurement properties of the three instruments compares favourably with that for the other instruments reviewed.

The three UK instruments are based on different approaches to the measurement of patient-reported health outcomes. The Diabetes Health Profile produces a profile of diabetes-specific health, and is based on the traditional psychometric approach to instrument development. The Audit of Diabetes Dependent Quality of Life incorporates an individualised importance weighting for each of 13 items. The Newcastle Diabetes Symptoms Questionnaire is a more narrowly focused measure of diabetes symptoms.

Key conclusions and recommendations

Three approaches to the measurement of patient-reported health outcomes should be considered for use in diabetes: generic instruments, disease-specific instruments and situation-specific instruments. Generic instruments are useful for comparisons across populations and have particular relevance to economic evaluation. Disease-specific instruments take account of the specific effects of diabetes on quality of life, and are likely to be more responsive to change than generic instruments. Situation-specific instruments are designed to measure the effects of specific interventions on knowledge, attitudes and behaviour.

Two instruments developed within the UK, namely the Diabetes Health Profile and the Audit of Diabetes Dependent Quality of Life, are recommended as potential primary outcome measures for clinical and health services research, including clinical trials. Where a clinically relevant and responsive measure of symptoms is required, it is recommended that the nine-item Newcastle Diabetes Symptoms Questionnaire be used alongside these instruments.

Where practical, the disease-specific instruments should be used alongside a validated generic instrument. The Well-being Questionnaire is recommended if a detailed evaluation of psychological well-being is required.

None of the instruments included in the review has the recommended levels of reliability for use in individual patients. Where an instrument is required for clinical practice at the group level, for example within clinical audit, it is recommended that the content of the Audit of Diabetes Dependent Quality of Life, the Diabetes Health Profile and the Newcastle Diabetes Symptoms Questionnaire is assessed for relevance.

Future quality of life research on diabetes should concentrate on evaluating and, where appropriate, refining existing instruments rather than developing new ones. There is a considerable body of literature relating to the quality of life of diabetes patients to support this work. The Audit of Diabetes Dependent Quality of Life, the Diabetes Health Profile and the Newcastle instrument require further testing for reliability, validity and responsiveness. In particular the instruments should be assessed concurrently for responsiveness to change. This research will inform decisions regarding the selection of instruments for future application.

A table with a summary description of the instruments reviewed follows.

***** Further information regarding reviews of instruments, analysis of individual measures, and recommendations can be found by referring to a full copy of the report, available in PDF format on the [PHI Group website](#) *****

Description of instruments

(from Tables V and VII of the report)

recommended instruments

<i>Name of instrument</i>	<i>No. items</i>	<i>Content</i>
Appraisal of Diabetes Scale	7	Diabetes: uncertainty, likely to worsen, developing life goals, coping Disease: upsetting Control of diabetes
Audit of Diabetes Dependent Quality of Life - asks patients to indicate how important each aspect of quality of life is	15	Physical ability General QoL, diabetes/general QoL Future worry/fear: personal and family; motivation Social/friendship, family, sex, leisure, travelling, enjoyment of food Work Stigma: others
Diabetes Care Profile - scales of diabetes control, social and personal factors, and attitudes towards diabetes, only	234	Active Low blood sugar, high blood sugar, ketones, reasons for high blood sugar/low blood sugar Diabetes/treatment: normal activities, schedule, makes life difficult, able to do anything, effect on life, things going well Afraid re. disease, acceptance of disease, depressed, inferiority, handle feelings Going out/travelling, relationships, friends, time alone Financial; daily activities Life satisfaction Diet restrictive Disease management Self-care, attitude
Diabetes Health Profile	32	Diabetes/general QoL Tension/edgy; self-harm, no wish for life; lose temper, moody; depression; cry; worry/fear: social, re. disease; wish away diabetes; look forward to future Family; avoid going out; stay out late Food/diet: controls life; injection: planning schedule; problems with diet Attitude to food
Diabetes Health Status Questionnaire	26	Energy, physical health Diabetes: physical symptoms Current health ratings Emotional health
Diabetes Impact Measurement Scales	44	Muscular strength/endurance Vision, energy, sleep, faint/dizzy, nausea, appetite, bowel problems, thirst/polyuria, low blood sugar, tingling extremities Diabetes restrictive Worry: future, disease, general; optimism, depression, feel useful, feel things going well Family, sex, social/leisure Usual occupation, general performance Life satisfaction Medicine inconvenient, care worth the effort, monitoring inconvenient, food/diet restrictive Knowledge, perception, in control, food, able to follow recommendations

<i>Name of instrument</i>	<i>No. items</i>	<i>Content</i>
Diabetes Quality of Life	46	Using car/machinery, diabetes interferes with exercise Sleep, pain, physically ill, low blood sugar, polyuria Self-esteem, worry: social/vocational, worry: disease Family, social relations, sex, leisure Daily activities Appearance, life satisfaction, stigma: others Diet restrictive Time: exercising, check-ups, monitoring, managing disease; treatment; diet Knowledge
Diabetes Quality of Life Clinical Trial Questionnaire <i>- revised version</i>	10	Moderate/vigorous activity, walking, movement, self-care, car/machinery, diabetes interferes with exercise, physical activity: flexibility Vitality, sleep, tired, physically ill, vision, nausea, treatment pain, low blood sugar, polyuria, thirst, hunger, tingling in the extremities General health, spur of the moment activities Discouraged/despair; frustrated; nervous; feel down; happy; self-esteem; calm; weighed down; worn out; full of pep; afraid: health-related; worry: health-related, social/vocational, disease-related, appearance Family, relationship/friends, sex, leisure, social Daily activities Appearance, life in general, stigma: others Willingness: insulin treatment; control of diabetes; flexibility: diet Time: managing, check-ups, monitoring; treatment; diet: flexibility; time: exercising; diet: restricting; insulin treatment Knowledge, attitude to diabetes, perception
Diabetic Quality of Life Questionnaire	142 (57)	Diabetes/general QoL Worry: disease-related Social, insulin: social Insulin: daily activities Insulin: ease/convenience, injection: discomfort, injecting: self-conscious
Diabetes-Related Knowledge and Quality of Life Questionnaire	67	Vision, hearing Diabetes and lifestyle Depressed, loneliness, fear: treatment-related, nervous: disease-related, get upset: disease-related Family; diet: social, family Memory Stigma: treatment/monitoring Diet: difficulty; treatment: difficulty; treatment/monitoring: time; monitoring: difficulty, cost, bother Doctor communication Attitude Disease: perception

<i>Name of instrument</i>	<i>No. items</i>	<i>Content</i>
Diabetes-Specific Quality-of-Life Scale (10 DSQoLS items not shown here ask how important are particular aspects of treatment/quality of life)	64	Physical strength, spontaneous activity Thirst/dry mouth, blood sugar, low blood sugar, high blood sugar, complications, nervous/restless, tired, polyuria, physically unwell, physical complaints, infections/itching, weak/lazy Diabetes: future plans, need to think about diabetes, diabetes controls life Anxious: disease-related, worry: disease-related, depressed, anxious/threatened Free time/flexibility, family, travelling, social, hobbies Appearance, stigma: others, feel disabled Bothersome/burdensome: monitoring blood sugar, food plan, time on treatment, diet, diet spontaneity, diabetes supplies, insulin Diet flexibility, self-monitoring, medical consultations: time Food restricted, food: desire to eat without planning
Diabetes-39	39	Walking, steps, self-care Energy, weakness, vision, sleep, complications, lose control of sugar levels Other health problems, general restrictions, general QoL, diabetes/general QoL Stress, depressed; worry: financial; worry: future Family/friends, sex Household duties Stigma: others Medication; diet; treatment plan; exercise requirements; self-monitoring; controlling: time, diabetes Perception
Multidimensional Diabetes Questionnaire - scales of Interference and Severity only	41	Diabetes and: daily activities, limitation of general activity, interference with planning, schedule restriction Worry: disease-related Travelling, social, family Work
Newcastle Diabetes Symptoms Questionnaire	9	Thirst, shaky, blurred vision, faint, passing lots of water, hunger, sleepy, cold hands/feet, pins and needles
Quality of Life: Status and Change	-	Physical functioning, symptom, psychological wellbeing, social wellbeing, cognitive functioning, role activities, personal constructs
Questionnaire on Stress in Patients with Diabetes-Revised	45	Physical ability/activity Complications, wind, sweating, energy, pain, hypoglycaemia, physical distress, thirst Fear: alone; irritable; moody; serious; nervous; worry: family; guilt: non-compliance; worry: disease Travelling, sex, social, free time, family Daily activities Attractive, feel handicapped, stigma Self-monitoring: problem; restrictive diet: controlling; equipment; diet: lack of food Doctors: information, time, care Knowledge

<i>Name of instrument</i>	<i>No. items</i>	<i>Content</i>
Social Psychological Health States	28	Walking Sleep Nervous/restless, impatience Social/friends, leisure, family, stay home Household work, work/job
Type 2 Diabetes Symptom Checklist - <i>final version</i>	34	Thirst, voiding, energy, fatigue, sleepiness, shortness of breath, palpitations, aches/pain, vision, numbness, tingling in extremities, odd feeling in legs/feet Irritability, moodiness Dull head, concentration, attentiveness
Well-being Enquiry for Diabetics	60	Physical activity, using car/machinery Sleep, polyuria, hypoglycaemia, feel well, pain, sick Diabetes limits freedom Fear: disease, general, future; anxious: general; depressed/sad; worry: general; decision-making; trust yourself; confidence Sex, family, social relations, leisure, travel Normal activities Stigman: others, feel different Diet: limiting/burden; diet: difficult; treatment schedule: burden; time managing diabetes Dependence on others Attitude to food
Well-being Questionnaire - <i>22-item version</i>	22	Sleep, energy Calm/nervous, cope with life, feel useful, depressed/upset, cry, afraid, falling apart, well-adjusted Think clearly Life satisfaction, life full/interesting, enjoy/happy with life

Reviewed instruments

recommended instruments

Appraisal of Diabetes Scale

Audit of Diabetes Dependent Quality of Life

Diabetes Care Profile

Diabetes Health Profile

Diabetes Health Status Questionnaire

Diabetes Impact Measurement Scales

Diabetes Quality of Life

Diabetes Quality of Life Clinical Trial Questionnaire

Diabetic Quality of Life Questionnaire

Diabetes-Related Knowledge and Quality of Life Questionnaire

Diabetes-Specific Quality-of-Life Scale

Diabetes-39

Multidimensional Diabetes Questionnaire

Newcastle Diabetes Symptoms Questionnaire

Quality of Life: Status and Change

Questionnaire on Stress in Patients with Diabetes-Revised

Social Psychological Health States

Type 2 Diabetes Symptom Checklist

Well-being Enquiry for Diabetics

Well-being Questionnaire

Related publications

Garratt AM, Schmidt L, Fitzpatrick R. (2002) Patient-reported health outcome measures for diabetes: a structured review. *Diabetic Medicine*; 19:1-11

User Groups

Work in progress

AM

14 September 2005

**These pages are under constant review.
We welcome constructive feedback and suggestions for appropriate
links, user groups etc.**