**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 **
<table>
<thead>
<tr>
<th>Name of instrument</th>
<th>No. items</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appraisal of Diabetes Scale</td>
<td>7</td>
<td>Diabetes: uncertainty, likely to worsen, developing life goals, coping Disease: upsetting Control of diabetes</td>
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<tr>
<td>Audit of Diabetes Dependent Quality of Life - asks patients to indicate how important each aspect of quality of life is</td>
<td>15</td>
<td>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</td>
</tr>
<tr>
<td>Diabetes Care Profile - scales of diabetes control, social and personal factors, and attitudes towards diabetes, only</td>
<td>234</td>
<td>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</td>
</tr>
<tr>
<td>Diabetes Health Profile</td>
<td>32</td>
<td>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</td>
</tr>
<tr>
<td>Diabetes Health Status Questionnaire</td>
<td>26</td>
<td>Energy, physical health Diabetes: physical symptoms Current health ratings Emotional health</td>
</tr>
<tr>
<td>Diabetes Impact Measurement Scales</td>
<td>44</td>
<td>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</td>
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<tr>
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<tr>
<td>Diabetes Quality of Life</td>
<td>46</td>
<td>Using car/machinery, diabetes interferes with exercise&lt;br&gt;Sleep, pain, physically ill, low blood sugar, polyuria&lt;br&gt;Self-esteem, worry: social/vocational, worry: disease&lt;br&gt;Family, social relations, sex, leisure&lt;br&gt;Daily activities&lt;br&gt;Appearance, life satisfaction, stigma: others&lt;br&gt;Diet restrictive&lt;br&gt;Time: exercising, check-ups, monitoring, managing disease; treatment; diet&lt;br&gt;Knowledge</td>
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<tr>
<td>Diabetes Quality of Life Clinical Trial Questionnaire - revised version</td>
<td>10</td>
<td>Moderate/vigorous activity, walking, movement, self-care, car/machinery, diabetes interferes with exercise, physical activity: flexibility&lt;br&gt;Vitality, sleep, tired, physically ill, vision, nausea, treatment pain, low blood sugar, polyuria, thirst, hunger, tingling in the extremities&lt;br&gt;General health, spur of the moment activities&lt;br&gt;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&lt;br&gt;Family, relationship/friends, sex, leisure, social&lt;br&gt;Daily activities&lt;br&gt;Appearance, life in general, stigma: others&lt;br&gt;Willingness: insulin treatment; control of diabetes; flexibility: diet&lt;br&gt;Time: managing, check-ups, monitoring; treatment; diet: flexibility; time: exercising; diet: restricting; insulin treatment&lt;br&gt;Knowledge, attitude to diabetes, perception</td>
</tr>
<tr>
<td>Diabetic Quality of Life Questionnaire</td>
<td>142 (57)</td>
<td>Diabetes/general QoL&lt;br&gt;Worry: disease-related&lt;br&gt;Social, insulin: social&lt;br&gt;Insulin: daily activities&lt;br&gt;Insulin: ease/convenience, injection: discomfort, injecting: self-conscious</td>
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<tr>
<td>Diabetes-Related Knowledge and Quality of Life Questionnaire</td>
<td>67</td>
<td>Vision, hearing&lt;br&gt;Diabetes and lifestyle&lt;br&gt;Depressed, loneliness, fear: treatment-related, nervous: disease-related, get upset: disease-related&lt;br&gt;Family; diet: social, family&lt;br&gt;Memory&lt;br&gt;Stigma: treatment/monitoring&lt;br&gt;Diet: difficulty; treatment: difficulty; treatment/monitoring: time; monitoring: difficulty, cost, bother&lt;br&gt;Doctor communication&lt;br&gt;Attitude&lt;br&gt;Disease: perception</td>
</tr>
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</table>
| 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                                                                                                                                                                                                 |
<table>
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<tr>
<td>Social Psychological Health States</td>
<td>28</td>
<td>Walking, Sleep, Nervous/restless, impatience, Social/friends, leisure, family, stay home, Household work, work/job</td>
</tr>
<tr>
<td>Type 2 Diabetes Symptom Checklist - final version</td>
<td>34</td>
<td>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</td>
</tr>
<tr>
<td>Well-being Enquiry for Diabetics</td>
<td>60</td>
<td>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, Stigma: others, feel different, Diet: limiting/burden; diet: difficult; treatment schedule: burden; time managing diabetes, Dependence on others, Attitude to food</td>
</tr>
<tr>
<td>Well-being Questionnaire - 22-item version</td>
<td>22</td>
<td>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</td>
</tr>
</tbody>
</table>
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


User Groups

Work in progress

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