Beyond blood glucose / The Diabetes Health Profile – Measuring the patients perspective of the benefits of diabetes interventions

Dr Keith Meadows
DHP Research & Consultancy Ltd
Diabetes in the U.K.

**UK Diagnosed**

2.9 million diagnosed with diabetes by 2011

**Diabetes type**

- **10%** of people with diabetes have Type 1
- **90%** of people with diabetes have Type 2

**Financial costs**

£192 million a week spent by the NHS

**The impact**

- **52%** Deaths due to cardiovascular disease
- **21%** Type 1 Deaths due to kidney disease
- **70%** Of people die within 5 years of an amputation
Diabetes in the U.K.

The number of people in Britain suffering from Diabetes without knowing it would fill the 2012 Olympic stadium over 6 times.

In 2011, one in every 400 to 600 children were diagnosed with diabetes...
The Psychological Impact of Living with Diabetes

The facts

According to Diabetes UK, people with diabetes are twice as likely to experience depression...

...and the risk is higher for women than for men.

"Yet there is little routine psychological support for people with diabetes.”

Diabetes UK

10% of the population in Britain have depression at any one time.
The Psychological Impact of Living with Diabetes

ANXIETY

aggression

Denial

Eating problems

POOR QUALITY OF LIFE

treatment non-adherence

disruption to social and professional life
Diabetes-specific PROs in a Real World Setting

- Efficacy of treatment
- Need for real world data driven by changing regulatory environment, drug safety and efficacy
- Identification of factors leading to treatment non-adherence and drug ineffectiveness
- Enables clinicians to tailor treatment regimens based on patient needs
- Increase treatment adherence as part of patient support programmes
The Diabetes Health Profile (DHP),
a multidimensional, diabetes-specific (T1 and T2), patient self-report outcome measure of the psychological and behavioural impact of patients living with diabetes.
Provisional development of the DHP

• A review of the literature.

• In-depth interviews with 45 diabetes patients analysed using a thematic approach.

• Examination of existing instruments of psychosocial functioning.

• Discussions with health care professionals (diabetologists), Diabetes Specialist Nurse (DSN) and dieticians.
The Diabetes Health Profile

The conceptual model

diabetes

Management - Treatment - Symptoms - Diet - Complications

Impact

Emotional - Mood - Limitations in social/work functioning - Eating behaviour

Anxiety
Provisional development of the DHP

4500 T1 & T1 Diabetes Patients

Psychometric analysis
- Factor analyses
- Cronbach’s alpha
- Construct validity etc.

Psychological distress
Barriers to activity
Disinhibited eating
Conceptual Framework for the DHP-1 and DHP-18

DHP-1 Conceptual framework
- Depressed due to diabetes
- Lose temper/shout due to diabetes
- Wished dead
- Feels like crying due to diabetes
- Lose temper over small things
- Wished never born
- Touchy about diabetes
- Arguments at home
- Wish diabetes would go away
- Throw things when upset
- Lose temper over diet/testing
- Hurt self when upset
- Tension headaches
- Look forward to the future

Psychological distress
- Days tied to meal times
- Plan days around injections
- Difficult staying out late
- Nagging fear of hypos
- Food controls life
- Edgy when out
- Worry about diabetic coma
- Avoid going too far incase of hypo
- Worry about going into hypo
- Avoid going out if sugars on low side
- Worry about colds and flu
- Difficult doing things due to diabetes
- Frightened busy/crowded shops

Barriers to activity
- Not easy to stop eating
- Hard saying no to food
- Eat to cheer self up
- Eat extra when bored/fed up
- Wished not so many nice things to eat

Disinhibited eating
- Eat to cheer self up
- Hard saying no to food
- Easy to stop eating
- Wish not so many nice things to eat

DHP-18 Conceptual framework
- Depressed due to diabetes
- Lose temper/shout due to diabetes
- Lose temper over small things
- More arguments at home
- Moody due to diabetes
- Lose temper over testing

Psychological distress
- Get edgy when nowhere to eat
- Avoid going out when sugars are low
- Worry about going into busy shops
- Days tied to meal times
- Food controls life
- Difficult staying out late
- Worry about colds and flu

Barriers to activity
- Eat to cheer self up
- Hard saying no to food
- Easy to stop eating
- Eat extra when bored/fed up

Disinhibited eating
- Eat extra when bored/fed up
- Wish not so many nice things to eat
## The Diabetes Health Profile (DHP)

<table>
<thead>
<tr>
<th>Administer</th>
<th>DHP-1</th>
<th>DHP-18</th>
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<tbody>
<tr>
<td>Type 1 Diabetes Individuals</td>
<td>16 years and older</td>
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<td>Reading Level</td>
<td>6th grade</td>
<td>6th grade</td>
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<td>Scales (No of items)</td>
<td>Psychological distress (14)</td>
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<td>Barriers to activity (13)</td>
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<td></td>
<td>Disinhibited eating (5)</td>
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<td>Response options</td>
<td>Four-point adjectival scales</td>
<td>Four-point adjectival scales</td>
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<td>Formats</td>
<td>Paper-and-pencil, interview</td>
<td>Paper-and-pencil interview, electronic hand held, tablet, IVR, web</td>
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<tr>
<td>Scoring</td>
<td>Items scores 0-3 in each dimension summed &amp; transformed to produce</td>
<td>Items scores 0-3 in each dimension summed &amp; transformed to produce</td>
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<tr>
<td></td>
<td>score 0 (no dysfunction to 100)</td>
<td>score 0 (no dysfunction to 100)</td>
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<tr>
<td>Completion time</td>
<td>9–12 minutes</td>
<td>5–6 minutes</td>
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<td>DHP manual, research support, training and workshops*</td>
<td>DHP manual, research support, training and workshops**</td>
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<td>FAQs</td>
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<td>Yes (see below)</td>
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# Development of the Diabetes Health Profile

<table>
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<tr>
<th>Appraisal component</th>
<th>DHP-1</th>
<th>DHP-18</th>
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<tbody>
<tr>
<td>Reproducibility</td>
<td>★</td>
<td>★</td>
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<td>Internal consistency</td>
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<tr>
<td>Content validity</td>
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<td>Construct validity</td>
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<td>Responsiveness</td>
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<td>★</td>
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<td>Interpretability</td>
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<td>★</td>
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<tr>
<td>MID</td>
<td>0</td>
<td>★</td>
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<tr>
<td>Floor/ceiling effects</td>
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<td>★★★★</td>
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<tr>
<td>Acceptability</td>
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<td>★★★</td>
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<tr>
<td>Feasibility</td>
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<tr>
<td>Cost utility analysis</td>
<td>0</td>
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0 Not reported  ★ Some limited evidence  ★★ Some good evidence in favour  ★★★ Good evidence in favour
More than 12,000 Type 1 & Type 2 Respondents Have completed the DHP-1 / DHP-18
Typical Applications of the DHP

• **Measure improvement or decline** in the psychological and behavioural functioning of patients

• **Screen** for unmet need

• **Demonstrate** drug efficacy

• **Assess** treatment effectiveness

• **Assess** intervention programmes

• **Enhance** treatment adherence by improving communication between you and your patients
Translations

- Bulgarian
- Croatian
- Czech
- Danish
- Dutch
- Dutch (Belgium)
- English (Canada)
- English (USA)
- Finish
- French
- French (Belgium)
- French (Canada)
- French (Swiss)
- German
- German (Austria)
- German (Swiss)
- Hungarian
- Italian
- Italian (Swiss)
- Mandarin
- Norwegian
- Polish
- Romanian
- Turkish (German)
- Slovak
- Slovenian
- Spanish
- Spanish (USA)
- Swedish
Modes of Administration
Pilot study of patient reported outcome measures (PROMs) in primary care

UK Department of Health
DHP-18 % Response Rates

33 General practices    1121 Questionnaires (Baseline)
424 Questionnaires (Follow-up)

Overall response rate
- 40    75.7

Response rate (London)
- 30.5   67.9

Response rate (NWE)
- 50.1   80.7

### Response rates by LTC

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<tr>
<th>Condition</th>
<th>Baseline</th>
<th>Follow-up</th>
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<td>Heart failure</td>
<td>50</td>
<td>66.2</td>
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<tr>
<td>COPD</td>
<td>49.2</td>
<td>71.4</td>
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<tr>
<td>Diabetes</td>
<td>40</td>
<td>75.7</td>
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<tr>
<td>Stroke</td>
<td>36.4</td>
<td>74.5</td>
</tr>
<tr>
<td>Epilepsy</td>
<td>34</td>
<td>74.5</td>
</tr>
<tr>
<td>Asthma</td>
<td>30</td>
<td>73</td>
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</table>

% of missing data for the EQ5D and DHP

<table>
<thead>
<tr>
<th>Measure</th>
<th>Baseline</th>
<th>Follow-up</th>
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</thead>
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<tr>
<td>DHP-18</td>
<td>0.9-2.5</td>
<td>1.6-2.2</td>
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<tr>
<td>EQ5D</td>
<td>5.0</td>
<td>4.4</td>
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<td>EQ5DVAS</td>
<td>1.2-3.1</td>
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What does the Diabetes Health Profile tell us about living with diabetes?
DHP-18 Domain scores by comorbidity

N=1802 (45% RR) T1 & T2 diabetes general practice patients

- Disinhibited eating
- Barriers to activity
- Psychological distress
Living with diabetes - Interpreting the DIABETES HEALTH PROFILE (DHP)

- 3173 patients completed the questionnaire.
- 91% Type 2 and 9% Type 1
- 55% M, 45% F
- Mean age: 63.9 years

Patients (mean) scores on the Disinhibited eating domain by BMI

- BMI <25: 47.8
- BMI 25-34: 49.2
- BMI >35: 52.4

Patients reporting severe hypoglycaemic episodes are tied to meal times:

77% of patients experiencing three severe hypoglycaemic episodes reported their days are tied to meal times.

59% of patients experiencing one severe hypoglycaemic episode reported their days are tied to meal times.

Factors associated with psychological and behavioural functioning in people with type 2 diabetes living in France. Stephanie Boini, Marie-Line Erpelding et al. Health Quality of Life Outcomes 2010, 8:124
Getting an in-depth look at diabetes with the DHP-18

Psychological distress
- Comorbidity
- Severe hypoglycaemia
- Female
- > Age
- Visit to the psychiatrist

MOST AT RISK

Barriers to activity
- Severe hypoglycaemia
- Other health issues
- Visit to the psychiatrist

MOST AT RISK

Disinhibited eating
- Younger women
- Forgetting to take insulin
- Unaware of HbA1 level
- Visit to the psychiatrist

MOST AT RISK

Factors associated with psychological and behavioural functioning in people with type 2 diabetes living in France. Stephanie Boini, Marie-Line Erpelding et al. Health Quality of Life Outcomes 2010, 8:124

Food controls life
- Yes 69%

Hard saying no to food you like
- Yes 69%

Eat to cheer self up
- Yes 53%

Depressed due to diabetes
- Yes 50%

Representing high scores
- Frequent and or substantial emotional stress including: dysphoric mood, irritability and externally directed hostility.
- PD

- Very significant levels of anxiety restricting behaviour and perceived limitations in social/role activities.
- BA

- Substantial and or frequent levels of eating in response to food cues and emotional arousal.
- DE
Recent Developments
Interpreting the Diabetes Health Profile

The minimally important difference (MID) is the smallest score difference on the Diabetes Health Profile that represents the minimal clinically significant difference.

Investigating the minimally important difference of the Diabetes Health Profile (DHP-18) and the EQ-5D and SF-6D in a UK diabetes mellitus population. Mulhern B and Meadows K. Health 5: 1045-1054, 2013
A longitudinal dataset from a UK community-based postal survey carried out in one health authority area

- 1092 respondents with a reported diagnosis of Type 1
- Type 2 (n = 999) diabetes...

who fully completed the EQ-5D, SF-6D and DHP-18 at both baseline and 1-year follow-up.

Investigating the minimally important difference of the Diabetes Health Profile (DHP-18) and the EQ-5D and SF-6D in a UK diabetes mellitus population. Mulhern B and Meadows K. Health 5: 1045-1054, 2013
Interpreting the Diabetes Health Profile

The required MID change in score for the DHP-18 domains

- Psychological distress: 7 - 11
- Barriers to activity: 6.5 - 9.9
- Disinhibited eating: 7.5 - 11.4

Investigating the minimally important difference of the Diabetes Health Profile (DHP-18) and the EQ-5D and SF-6D in a UK diabetes mellitus population. Mulhern B and Meadows K. Health 5: 1045-1054, 2013
• Preference-based scoring using DHP-3D and DHP-5D item scale derived from the DHP-18

• DHP-3D & DHP5D is able to estimate QALYs for the assessment of diabetes specific interventions in existing datasets or in future trials that include the DHP-18 or DHP-1

• The DHP-5D is able to estimate QALYs in data or trials where the DHP-1 and SF-36 are included

Development of an e version of the DHP

Image source: CRF Health
“An Author pre-approved instrument qualifies the migrated instrument to the author’s level of quality and expectation. **Elan Josielewski (Mapi)**

Having followed good practices in instrument migration, it is considered that an Author pre-approved instrument would, with reasonable testing (in line with industry guidelines), demonstrate equivalence.”

**David Churchman (Oxford University Innovation)**
Advantages of an eDHP

- Facility to apply computerised adaptive scoring
- Collection of symptom events etc. on the same electronic platform
- Real-time DHP-18 scores benchmarked against age, gender, diabetes type, acute complications e.g. hypoglycaemic episodes
Integration of the DHP-18 into holistic assessment of needs programme for Type 1 and Type 2 patients.
KEY ATTRIBUTES: The Diabetes Health Profile

- **Developed** with significant patient input
- **A clearly defined conceptual framework** of the measurement model which conforms to the FDA Final guidance for Industry
- **The measurement of dysfunctional eating behaviour** – which despite its importance in the management of diabetes is absent in other scales
- **Content** No hypothetical questions, relates to real life experiences which respondents identify and engage with
- **Suitable** for use in range of research settings including population surveys, phase III and real world data collection
- **Minimum Important Difference (MID)** Values available
- **Now available** as an eDHP Author approved
- **Now available** - preference-based measures for diabetes: DHP-3D and DHP-5D