### Introduction

- Diabetes is a chronic disorder of the endocrine system affecting more than 300M people worldwide. For the person with diabetes potential outcomes include both acute and chronic incapacitating complications such as hypoglycaemia, blindness and kidney disease and premature death as well as the psychological and social impact on everyday life which in turn can affect therapy adherence.
- In diabetes, patient reported outcome (PRO) measures are increasingly used in clinical trials and patient care to assess subjective psychosocial functioning and health related quality of life.
- The application of information at the individual patient level – tailored therapeutics – can lead to substantial improvements in patient outcomes and improve the predictability of therapeutic response and clinical success.
- It is important to understand the relationship between self-reported PRO measures and objective clinical indicators, and also which PRO dimensions are predictive when assessing change over time.
- The aim of this study is to assess the relationship between the Diabetes Health Profile (DHP-18) and objective clinical indicators to investigate if the measure can be used to identify specific populations and individual patients with diabetes for whom treatment will lead to better health outcomes.

### Methods

#### The Diabetes Health Profile (Meadows et al., 2000):

- Assesses psychosocial functioning in Type 2 diabetes across three domains: Psychological Distress (7 items); Barriers to Activity (6 items); Disinhibited Eating (5 items).
- It is important to understand the relationship between self-reported PRO measures and objective clinical indicators, and also which PRO dimensions are predictive when assessing change over time.
- The Diabetes Health Profile (Meadows et al., 2000):
  - Psychological Distress (7 items);
  - Barriers to Activity (6 items);
  - Disinhibited Eating (5 items).

#### Sample:

- A large sample of Type 1 and Type 2 people with diabetes (n=1,802) collected in one United Kingdom health authority area was used (Table 1).
- Data was collected longitudinally at two time points (baseline and one year follow up).
- Subsamples of the data were used for each regression model based on the number of respondents reporting clinical concerns across the timepoints used.

#### Analysis:

- The relationship between the DHP-18 and a number of variables, including diabetes specific and co-morbid health complications and length of time diagnosed were assessed. This was done cross-sectionally and longitudinally.
- Descriptive analysis of those reporting clinical concerns, and change in presence of absence of clinical concerns over time, was carried out.
- Ordinary least squares regression was used to assess the relationship between DHP dimension scores (dependent variables) and clinical indicators (independent variables).

### Results

#### Relationship between baseline DHP scores and clinical indicators:

- Psychological distress scores are significantly associated with eye and foot related complications and co-morbid conditions including depression.
- Barriers to activity scores are significantly associated with duration of diabetes, eye and foot related complications and a range of co-morbid conditions including depression and lung disease.
- Disinhibited eating scores are significantly associated with duration of diabetes, the number of associated problems and co morbid conditions such as bone and lung disease.

#### Relationship between change in DHP score and change in presence of clinical conditions:

- The DHP dimension scores are significantly associated with change in levels of anxiety and depression, but evidence is more mixed across the other clinical indicators.

### Conclusions

- This study had demonstrated that higher scores (increasing dysfunction) on the psychological distress, perceived barriers to activity and disinhibited eating domains of the Diabetes Health Profile (DHP-18) are statistically associated with a range of variables, including diabetes-related complications, comorbidity and duration of diabetes. There was also initial evidence of an association between change in DHP-18 domain scores and change in severity of some clinical conditions.
- These findings indicate that the DHP-18 might be an appropriate diabetes specific patient reported outcome measure for predicting therapeutic response and clinical success in some health areas.

---

**Table 1**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>N (%) reporting</th>
<th>Psychological Distress</th>
<th>Barriers to activity</th>
<th>Disinhibited Eating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetic complications</td>
<td>Diabetes</td>
<td>Other</td>
<td>Diabetes</td>
<td>Other</td>
</tr>
<tr>
<td>Time with diabetes</td>
<td>59</td>
<td>8.13**</td>
<td>7.04*</td>
<td>4.13**</td>
</tr>
<tr>
<td>Foot complications</td>
<td>62</td>
<td>1.96</td>
<td>6.49*</td>
<td>2.67</td>
</tr>
<tr>
<td>Kidney complications</td>
<td>5</td>
<td>2.67</td>
<td>2.07</td>
<td>1.54</td>
</tr>
</tbody>
</table>

**Table 2**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>N (%) reporting</th>
<th>Psychological Distress</th>
<th>Barriers to activity</th>
<th>Disinhibited Eating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetic complications</td>
<td>Diabetes</td>
<td>Other</td>
<td>Diabetes</td>
<td>Other</td>
</tr>
<tr>
<td>Time with diabetes</td>
<td>59</td>
<td>8.13**</td>
<td>7.04*</td>
<td>4.13**</td>
</tr>
<tr>
<td>Foot complications</td>
<td>62</td>
<td>1.96</td>
<td>6.49*</td>
<td>2.67</td>
</tr>
<tr>
<td>Kidney complications</td>
<td>5</td>
<td>2.67</td>
<td>2.07</td>
<td>1.54</td>
</tr>
</tbody>
</table>

---

1 School of Health and Related Research, University of Sheffield, Sheffield, UK
2 DHP Research & Consultancy Ltd, Banbury, UK
3 Isis Outcomes, Isis Innovation Ltd., Oxford, UK


For more information visit www.diabetesprofile.com or e-mail kmeadows@dhpresearch.com