

The Diabetes Health Profile eBook

DEVELOPMENT AND APPLICATIONS v.2

Health Outcomes Insights Ltd

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1 Summary

Measurement of the psychological and behavioural functioning of the patient is central to the understanding and describing the impact of the disease and its treatment.

As with other diseases there has been over the past two decades a significant shift in focus from the biochemical and physical measurement such as blood glucose levels in the care and treatment of the patient with diabetes to one of self-report by the patient as to their perceptions of the illness and outcomes from treatment.

The Diabetes Health Profile (DHP), first published in 1996 (Meadows *et al* 1996), was one of the first diabetes-specific patient reported outcome (PRO) measures developed to assess the psychological and behavioural outcomes as a result of living with diabetes.

The DHP was developed with significant patient and clinical input to represent a model of patient reported outcomes not previously included in other diabetes-specific instruments, such as the disinhibited eating domain.

Sanctioned by the UK Department of Health their for their Long Term Condition Patient reported outcome measures (PROMS) Programme the DHP has been extensively administered across a range of settings including clinical trials, academic research and population and community surveys to more than 15.000 people with either Type 1 or Type 2 diabetes, where it has demonstrated sound psychometric properties and operational performance as well as being highly acceptable to patients.

Available in more than 30 languages, use of the DHP is supported by a comprehensive user manual and a norm-referenced data set together with information on the minimal important difference (MID).

2 Why measure?

The importance of the psychological and behavioural function and health-related quality of life (HRQoL) over the past decade or so has gained significant prominence in the treatment and care of the patient.

The impact on patient's quality of life resulting from having diabetes is significant, first, because patients tell us that the way they feel is important to them and secondly, from research we know that better emotional and psychological health leads to better self-care and health outcomes. Whereas, blood glucose and HbA1 levels can inform us about how good or bad the patient's glycaemic control is, what they cannot tell us is how the patient is feeling and the impact this might be having on adherence to treatment.

3 What is the DHP?

The Diabetes Health Profile (DHP) is a disease-specific instrument developed to capture prospectively the impact of living with diabetes has on the patient's psychological and behavioural functioning (Meadows *et al* 1996; Meadows *et al* 2000).

The rationale for the development of the DHP-1:

- to find a critical set of questions that could be rated by people with diabetes most efficiently without too much expenditure in time
- to be based on a clear and explicit conceptual model and framework (measurement model)
- the content to be contextually and situation specific to diabetes and reflect issues considered important by the patient
- the measured constructs to have the ability to be influenced by treatment or medical care and therefore, of relevance to the health care professional, clinical trialists and researcher.

4 What the DHP measures

The DHP is typically used in one of two formats. The DHP-1 which was developed for use with Type 1 and Type 2 (insulin requiring patients) comprises 32 items (Meadows *et al* 1996) which are summed to provide three domain scores measuring:

- **Psychological distress** – (14-items) (dysphoric mood, feelings of hopelessness, irritability, self-harm, feeling of external hostility)
- **Barriers to activity** (13-items) (perceived limitation to activity, operant anxiety)
- **Disinhibited eating** (5-items) (lack of eating control, response to food cues and emotional arousal).

Early in the year 2000 the DHP-1 was adapted for use with Type 1 and Type 2 (all treatment modalities: insulin requiring, oral and diet treatment). This version appears to have received the widest attention and use and is referred to as the DHP-18. (Meadows *et al* 2000).

As with the DHP-1 the DHP-18 measures the three domains:

- **Psychological distress (6-items)**
- **Barriers to activity (7-items)**
- **Disinhibited eating (5-items)**

For both the DHP-1 and DHP-18 a number of different “forced choice” adjective scales are used to measure either frequency or intensity depending on the nature of the question asked.

5 Development of the DHP

Based on the transactional model of stress and coping (Lazarus & Folkman, 1984) together with interviews with diabetologists, diabetes specialist nurse (DSN's) and dieticians, patients, review of the literature and previous research by the author, a theoretical/conceptual framework was developed to provide a frame of reference for the in-depth interviews with patients for uncovering patterns of patient behaviour and emotional state within a context of day to day living with diabetes.

Together with a thematic analysis of interviews with patients, review of the literature and use of the parallel-approach method to examine the hypothesised question groupings the original DHP-1 evolved following numerous iterations including subjective and statistical evaluations, health professionals and patient feedback. (Meadows *et al* 1996).



6 Validating the DHP

Validation of the DHP-1 was based on the then current psychometric standards found in a number of texts including (Anastasi, 1961; Campbell & Fiske, 1959; Cattell, 1978; Cronbach, 1951; Cronbach & Meehl, 1955; Guildford, 1954) which were used as a guide to scale construction.

These standards include the elements of validity (content, criterion, discriminant and construct validity) and reliability (internal consistency and test-retest) and are very similar to those proposed by the FDA's Guidance for Industry, *Patient-reported Outcome Measures: Use in Medical Product Development to Support Labelling Claims* (FDA 2009). Both the DHP-1 and DHP-18 have demonstrated high levels of content validity via patient focus groups and feedback. Construct and discriminant validity as well as reliability have been demonstrated in a number of early studies (Meadows *et al* 1996; Goddijn *et al* 1996; Meadows *et al* 2000; Erpelding *et al* 2009;).

7 Applications

Both the DHP-1 and DHP-18 have been used in a range of different studies including clinical trials such as a 16-week, randomized, open-label, parallel-group trial conducted in Russia to compare biphasic insulin as given three times daily or twice daily in combination with metformin versus oral antidiabetic drugs alone in patients with poorly controlled type 2 diabetes (Ushakova *et al* 2007).

Currently the DHP-18 is employed by the UK Department of Health. Academic studies includes the TELFIT Study assessing the reinforcement of the Impact of a Functional Insulin Therapy Training Course by Telemonitoring; The Whole Systems Demonstrator Trial which is comprehensive evaluation of the impact of telemonitoring in patients with long-term conditions and social care needs.

The DHP has also been employed in population-based studies including a cluster randomized, non-inferiority trial, by self-administered questionnaires in 55 Dutch primary care practices (Clevering *et al* 2007; Gorter *et al* 2007); the Entred study investigating the demographic and clinical factors associated with psychological and behavioural functioning in people with Type 2 diabetes living in across France (Erpelding *et al* 2009). A community based survey of changes in health status of

patients with diabetes in Bridgend, South Wales (Farr *et al* 2010); a national survey in the Netherlands to assess the preferences of patients with Type 2 diabetes regarding self-care activities and diabetes education (Gorter *et al* 2007). Studies in primary care has included a study of sex inequalities in access to care for patients with diabetes in primary care (Hippisley-Cox *et al* 2006). Pilot Study of using PROMs in LTC in General Practice (Peters *et al* 2013).

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

8 Available translations

language versions of the Diabetes Health Profile have undergone extensive linguistic validation in accordance with currently accepted methodology accepted by international groups, ISPOR guidelines and the standards accepted by regulatory agencies such as the FDA. All new translations must undergo the appropriate procedures in accordance with currently accepted methodology and guidelines which will include forward and backward translations by native speakers, pilot testing with cognitive debriefing and international harmonization to ensure conceptual equivalence and proof reading by native translators.

DHP-1	DHP-18
-	Bulgarian
-	Croatian
-	Czech
Danish	Danish
Dutch	Dutch
Dutch (Belgium)	Dutch (Belgium)
English (Canada)	English (Canada)
English (USA)	English (USA)
Finnish	Finnish
French	French
French (Belgium)	French (Belgium)
French (Canada)	French (Canada)
-	French (Swiss)
German	German
-	German (Austria)
-	German (Swiss)
-	Hungarian
Italian	Italian
-	Italian (Swiss)
-	Mandarin
-	Norwegian
-	Polish
-	Romanian
Turkish (German)	Turkish (German)
-	Slovak
-	Slovenian
Spanish	Spanish
Spanish (USA)	Spanish (USA)
Swedish	Swedish

9 Administering the DHP

Both the DHP-1 and DHP-18 can be administered in a number of formats, including traditional “paper-and-pencil” (either self-administration or research/clinical staff) and electronic formats (ePRO) such as telephone-based interactive voice response (IVR) systems, hand held devices, PC tablets, and Web-based applications.

An Author pre-approved eDHP-18

The DHP-18 TrialMax edition is author pre-approved and ready to deploy following rapid validation through Oxford Innovation’s accelerated equivalency program. The DHP-18 TrialMax edition takes advantage of the TrialMax eCOA platform’s usability and patient retention enhancements for improved efficiency in collecting clinical outcome data directly from patients and sites during Diabetes trials.

The DHP-18 TrialMax edition offers:

- Reduced patient and site burden through a user interface design with extensive usability testing, allowing integration in eCOA programs with multiple questionnaires, while maintaining consistent interface and navigation
- Increased patient engagement with the ability to send SMS and email reminders to patients across all TrialMax eCOA solutions
- Automated scoring build onto the reporting portal to support tailored therapeutic and patient support programs

10 Scoring the DHP

The scoring method, which is applied to the Diabetes Health Profile (DHP), is based upon the widely used Likert method of summated scales. Each question is scored using a graded scale of 0-3 with zero representing 'no dysfunction' and summated and transformed to provide a total score of 100 for each of the three domains.

When using the official version of the DHP-1 and DHP-18 each of the question responses has been pre-coded. It is these pre-coded question scores which must be used when calculating each domain scale. Using the officially scored version of the DHP will also ensure that where appropriate questions have been reversed scored.

The DHP is designed to obtain data relative to the frequency or intensity of the impact of living with diabetes on the psychological and behavioural functioning of the patient. However, the optimal selection of the recall period to provide an accurate picture of the patient's psychological and behavioural functioning can be challenging as the appropriate recall period must take account of the patient

burden and ability of the patient to easily and accurately recall the required information. Also within the same disease area, appropriate recall may vary depending on the measured concept or phenomenon of interest e.g. variability, frequency and intensity. Furthermore, as the underlying rationale was to collect prospective information on the patient's psychological and behavioural functioning, a given recall period was considered inappropriate.

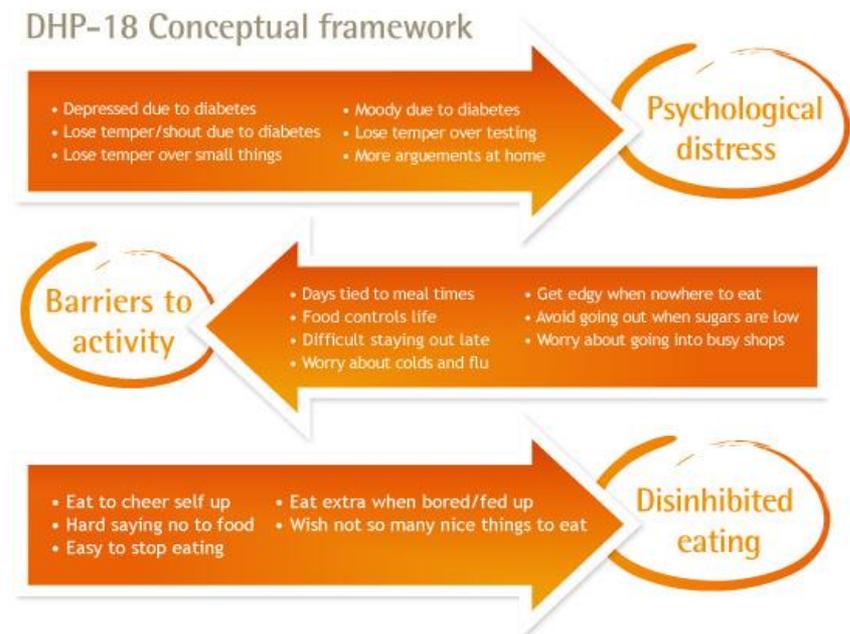
Based upon the above factors all the DHP questions are phrased in the present e.g. "Do you cry or feel like crying" enabling the respondent to provide their own frame of reference (context) using the range of available response options. Full details of the scoring algorithm including dealing with missing values and, questionnaires, norm-based scoring and using a reference population are available in the official manual.

11 Interpreting DHP scores

Both the DHP-1 and DHP-18 are scored to produce a score of zero (no dysfunction) to 100 (max dysfunction). Average scores that have been reported for the DHP-1 are 20.1, 24.7 and 32.2 for Psychological distress, Barriers to activity and Disinhibited eating respectively.

DHP-18 average reported scores are:

- Psychological distress (insulin 31.0), (tablet 21.5), (diet 12.9)
- Barriers to activity (insulin 30.0), (tablet 18.6), (diet 13.8)
- Disinhibited eating (insulin 37.4), (tablet 33.4), (diet 33.2)



11 Interpreting DHP scores

Meaning of low and high scores

Content-based guidelines for the interpretation of the three domains of the DHP-1 and DHP-18 are based on the descriptions of emotional and behavioural dysfunctioning associated with very low and high scores on the Psychological distress, Barriers to activity and Disinhibited eating domains of the DHP-1 and DHP-18.

Psychological distress

DHP-1: High scores for the DHP-1 PD dimension represent a combination of high levels of diabetes-related dysphoric mood, negative evaluation of the future, anger, irritability and externally directed hostility, high levels of family tension and an absence of general well-being and even-temperedness, diabetes-related depressed mood combined with high levels of irritability, loss of temper and family tensions. • High scores for the **DHP-18** PD dimension represent substantial levels of diabetes-related depressed mood combined with high levels of irritability, loss of temper and family tensions.

Barriers to activity

For both the **DHP-1 and DHP-18** high scores for the BA scale reflect very significant levels of general anxiety and interference with daily activities due to fear of hypoglycaemia. Low score levels represent an absence of anxiety and an ability to undertake social or usual role activities. The DHP-18 differs from the DHP-1 only in the number of items representing this dimension.

Disinhibited eating

For both the **DHP-1 and DHP-18** scores for the DE scale reflect a combination of eating behaviour as a consequence of emotional arousal and eating in response to food cues with high scores representing substantial and frequent lack of eating restraint.

11 Interpreting DHP scores

DHP-18 Minimum Important Difference (MID)

The MID is the smallest difference that is considered clinically important and is used as a benchmark to interpret for example mean score differences between treatment arms. A difference in mean scores between treatment arms in a clinical trial provides evidence of treatment benefits.

Recent research shows that MID estimates varied by domain, by estimation approach used, and by diabetes type. For type I diabetes the Psychological Distress domain estimates ranged from 2.86 to 11.05, Barriers to activity domain from 2.87 to 11.32 and Disinhibited Eating domain from 1.03 to 11.53.

For type II diabetes the Psychological Distress estimates ranged from 0.94 to 9.71; Barriers to Activity from 1.66 to 9.88 and Disinhibited Eating from 0.90 to 11.64. (Mulhern *et al* 2012(1)).

Preference-based measures

The DHP-3D and DHP-5D are diabetes-specific preference-based measures that can be used to generate utility values to produce quality adjusted life years (QALYs). DHP-3D utility values can be generated using data from the DHP-18. DHP-5D utility values require additional data from the DHP-1 + the SF36v2 item 31(tired).

The DHP-3D has 3 dimensions of (1) Mood, (2) Eating and (3) Social limitations. Utility values are generated using the DHP-18 data only. The DHP-5D comprises 5 dimensions (1) Mood, (2) Eating, (3) Social limitations, (4) Hypoglycaemic attacks and (5) Vitality.

13 End note

The increased focus on the collection of patient reported outcomes over the past two decades represents a major paradigm shift in the appreciation of the importance of the patient's perspective in the delivery of effective care and treatment.

The DHP is one disease-specific PRO measure with proven patient acceptability, sound psychometric properties and operational performance that provides an insight into the psychological and behavioural functioning of the patient as a consequence of living with diabetes. As outcome measurement increases in use we believe that the focus will be on the selection and use of a limited number of disease-specific instruments which are cognitively simple to complete, acceptable to patients, easy to score with established psychometrics that can provide interpretable findings.

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